**THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| IN RE HEMISPHERX BIOPHARMA, INC. LITIGATION | CIVIL ACTION NO.: 09-CV-05262-PD<br><br>CLASS ACTION |

# LEAD PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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Lead Plaintiff the Hemispherx Investor Group, consisting of Victor Cherry, Ehud Nahum, Jagvinder Pal Singh and Padmakar Boienipelly ("Lead Plaintiff" or "Plaintiffs") submits this memorandum in opposition to the motion by Defendants Hemispherx Biopharm, Inc. ("Hemispherx"), William A. Carter, M.D. ("Carter") and David R. Strayer, M.D. ("Strayer") to dismiss the Consolidated Class Action Complaint ("Complaint").[1]

## I. PRELIMINARY STATEMENT

Defendant Hemispherx is a biopharmaceutical company that, since approximately 1990, has been trying to obtain approval from the Food and Drug Administration ("FDA") to market Ampligen as a treatment for Chronic Fatigue Syndrome ("CFS"), a poorly understood disease with no known cause. Hemispherx filed its New Drug Application ("NDA") for Ampligen with the FDA on October 10, 2007, but the FDA rejected the NDA because it was "not substantially complete," and noted fourteen deficiencies in the NDA. Over the next six months, Defendants claimed they had addressed all of these deficiencies by submitting new reports to the FDA, culminating with their submission of an amended NDA on April 25, 2008. ¶ 38.[2] On July 7, 2008, after almost two decades of development and testing, the FDA finally accepted the filing of the Ampligen NDA and the review process began.

Pursuant to the Prescription Drug User Fee Act ("PDUFA"), the FDA is permitted six months to complete its review of an NDA. Because the approval or rejection of an NDA can have an enormous impact on the financial condition of a company sponsoring an NDA, analysts and investors eagerly anticipate the "PDUFA date" – the date by which the FDA must render its decision on whether to approve the NDA. In this case, the PDUFA date was initially set for

[1] Defendants Carter and Strayer are collectively referred to herein as the "Individual Defendants." Hemispherx and the Individual Defendants are collectively referred to herein as "Defendants".

[2] Citations to the Complaint are referred to as "¶__" herein.

February 25, 2009. However, on February 18, 2009, the first day of the Class Period, Hemispherx issued a press release disclosing that the PDUFA date for the NDA had been extended by the FDA from February 25, 2009 to May 25, 2009 because "[a]dditional data were received by the FDA within 3 months of the user fee goal date."[3]

Many more delays were to follow, but rather than fully disclose the reasons behind these delays – and thereby reveal the numerous deficiencies and additional questions raised by the FDA that were not cured by the amended NDA – throughout the Class Period,[4] Defendants made numerous false and misleading statements, shifting the blame for the delays to the FDA. Although the FDA had requested from Hemispherx extensive additional information that the agency deemed necessary to complete its review of the NDA – requests that were so extensive that Defendants needed to submit at least ten new reports to the FDA between March 2009 and December 2009 – Defendants repeatedly represented to the investing public that: "***we have answered all the major questions that have been put forward with the Agency;***" "***the major questions which they have asked have in our opinion been retired;***" ¶ 52, and "***[the FDA] did not request additional information from the Company at this time***." ¶ 65. Defendants also misled investors about critical issues concerning the safety and efficacy of Ampligen, stating that: "***[n]o safety concerns***" had been raised, with regard to Ampligen's cardiac effects; "***[o]verall death rates in CFS patients due to heary failure, suicide and cancer were reduced***;" ¶ 51, and results for the "intent to treat" analysis of the primary endpoint of Phase III Ampligen clinical trial, were "***statistically significant***." ¶ 68. Additionally, Defendants falsely blamed

[3] Appendix to Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiff's Consolidated Class Action Complaint ("Def. Appendix") Ex. 25.

[4] The Consolidated Complaint is brought on behalf of purchasers of Hemispherx common stock between February 18, 2009 and December 1, 2009 (the "Class Period").

these delays on the FDA's purported "***increased workload related to the recently enacted and implemented FDA Amendments Act***." ¶ 47.

These statements flew in the face of the facts that were then known to Defendants about the status of the NDA. Specifically, regardless of the FDA's workload, the FDA could not have possibly completed its review of the Ampligen NDA because, throughout the Class Period, Defendants were in the process of completing reports which the FDA had requested on critical topics, including clinical safety assessments, specialized pre-clinical toxicology, and chemistry and manufacturing controls. ¶ 48.

Defendants' knowledge or reckless disregard of the reasons for the delays in the FDA's ruling on the Ampligen NDA is demonstrated by numerous facts that support the requisite "strong inference" of scienter, including the following:

- Ampligen was the Company's core product, and obtaining approval for the Ampligen NDA was its most important project. ¶¶ 42-43.

- A former Hemispherx employee who worked directly with Defendant Carter from 1999 until the end of 2008 stated***, "[t]hat Dr. Carter tightly controlled the communication channel between Hemispherx and the FDA was an understatement. Everything went through him or not at all***." ¶ 86.

- This former employee also said, "Dr. Carter did not want any of the information that was going back and forth to the FDA regarding Ampligen to get out into public knowledge until he wanted it to get out." *Id*.

- The fact that Defendant Carter controlled all communications with the FDA is corroborated by two letters from the FDA, addressed directly to Defendant Carter rather than a lower level employee, in which the agency reprimanded Defendants for improperly making statements promoting Ampligen as a safe and effective drug for treatment of CFS prior to receiving marketing approval from the FDA. ¶¶ 113-115.

- Defendants Carter and Strayer led extensive discussions concerning the Ampligen NDA, that dominated Hemispherx's investor conference calls, both before and during the Class Period. ¶¶ 51-52, 54-56, 59, 66, 68, 71, 97-103.

- Defendants' admitted in Forms 10-Q filed with the SEC that Hemispherx's "success is dependent on the continued efforts of [its] staff, especially . . . Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen®, ***and his knowledge of our overall activities, including patents and clinical trials.***" ¶ 87.

Defendants were highly motivated to engage in fraud because, at the outset of the Class Period, the Company was strapped for cash and was forced to pay a portion of the salaries and fees of its Board of Directors, employees, consultants and vendors in its common stock. As a result of Hemispherx's decades long quest to obtain FDA approval of Ampligen for any indication, Hemispherx had incurred substantial operating losses every year since 1987. ¶ 40. Moreover, none of Hemispherx's products had ever produced substantial revenues and, as of March 31, 2009, the Company had an accumulated deficit of ***more than $200 million***. ¶ 41. Consequently, Hemispherx turned to raising funds by its only means: selling its securities. If Defendants had been unable to raise capital by deceiving unsuspecting investors, Defendant Carter would have been obligated to loan the Company up to $1 million of his own money, ¶ 83, and thus he had a compelling motive to commit securities fraud.

In this endeavor, Defendants were extremely successful. They raised more than $33.7 million from sales of Hemispherx securities on May 8, 2009 and May 18, 2009, and more than $28.1 million from the sale of Hemispherx securities on July 2, 2009, for a total of more than ***$61.8 million*** during the Class Period. ¶¶ 61, 63-64, 84-85. Through Defendants' false statements regarding the Ampligen NDA and their unrelenting hype of Ampligen, including Defendant Carter's statements that it was potentially "***a $1 billion product,"*** ¶ 45, Defendants artificially inflated the price of Hemispherx's common stock from $0.32 per share on the first

day of the Class Period, to $2.54 per share on July 2, 2009, when Hemispherx completed its third securities offering.

After announcing one delay after another, Defendants' fraud began to unravel on November 2, 2009, when Defendants shocked investors by revealing that, in response to ongoing FDA inquiries, since March 9, 2009, they had submitted "***six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports,***" and that they "***plan[ned] to submit four (4) additional reports on interrelated topics in November and December, 2009, which will include pharmacokinetic analyses in multiple lower animal species . . . .***" Upon this disclosure, the price of Hemispherx common stock plummeted 23%, from $1.45 per share on October 30, 2009 to close at $1.13 per share on November 3, 2009. ¶¶ 12, 122.

This collapse of Hemispherx's stock demonstrates that the investing public had been misled by Defendants' fraud. So too does the reaction of financial analysts to the Company's November 2, 2009 disclosures. Specifically, a November 3, 2009 article in *TheStreet.com* stated in part:

> Hemispherx Biopharma issued an "update" to the regulatory status of its chronic fatigue syndrome drug Ampligen in which ***the Company essentially admits that its prior public statements were false and misleading***.
>
> Monday's statement was likely crafted by Hemispherx's lawyers as a way to help CEO Carter wiggle out of public statements he made in May and June claiming the Ampligen application to the U.S. Food and Drug Administration was to be complete. ***Carter insisted regulators weren't asking for any additional information on Ampligen.***
>
> Carter made these statements both before and immediately after the FDA approval decision date for Ampligen on May 25, which came and went without any word from the agency. ***We now know that Carter's statements were***

> ***demonstrably false. The FDA application for Ampligen was not complete because several items were outstanding, the Company now states.*** These included FDA requests for data on Ampligen's safety both in humans and animals. The FDA also required additional information about Ampligen's manufacturing.

¶ 75 (emphasis added).

Finally, on December 1, 2009, Defendants disclosed that the FDA had advised the Company that it would not approve the Ampligen NDA because: (1) it lacked evidence of the efficacy of Ampligen (as determined by the lack of statistical significance of the treadmill test results); (2) it failed to provide evidence of cardiac safety; and (3) it lacked complete carcinogenicity studies.

Against this backdrop of brazen misrepresentations, Defendants now move to dismiss the Complaint based on their strained contention that the Complaint does not allege any false and misleading statements because Defendants had purportedly informed investors of the facts that underlie the Complaint – a defense commonly referred to as "truth-on-the-market."

However, because the "truth-on-the-market" defense involves highly fact-intensive inquiries about what the market knew or reasonably believed that are all but impossible to resolve at the pleading stage, this defense is inappropriate for consideration in the context of a Rule 12(b)(6) motion. For instance, resolving Defendants' truth-on-the-market defense would require a factual determination that the ***ten new reports*** – that Defendants later admitted were submitted only in response to FDA queries – were the same ones referred to in the various vague statements Defendants had made both before and during the Class Period about their purportedly ***voluntary*** submissions to the FDA. *See* Def. Br. at 15-43. In fact, investors simply could not have known that Defendants were in the process of preparing and submitting ***ten new reports*** to the FDA on a wide variety of clinical, pre-clinical and manufacturing issues that were ***required***

to be submitted before the FDA could complete its review, because Defendants were making contemporaneous statements to the contrary, including: "***we have answered all the major questions that have been put forward with the Agency,***" and that "***the major questions which they have asked have in our opinion been retired.***" ¶ 52.

Defendants further contend that regardless of whether they lied to investors, their statements should not have been relied upon because they were non-actionable statements of belief or opinion, forward-looking statements or mere "puffery." However, these arguments fare no better than Defendants' truth-on-the-market defense because they also require the resolution of questions of fact and therefore must be rejected at this stage of the litigation.

Finally, Defendants argue that the Complaint fails to plead a strong inference that Defendants acted with scienter, but only by misconstruing the abundant, compelling scienter allegations in the Complaint, which, viewed holistically, establish that Defendants both acted with actual knowledge or reckless disregard of the truth, and had concrete, personal motives to commit securities fraud.[5]

## II. STATEMENT OF FACTS

Hemispherx is a specialty pharmaceutical company engaged in the clinical development, manufacture and distribution of new drug therapies. ¶ 3. At all times relevant to this action, Ampligen, an experimental drug undergoing clinical development for treatment of CFS, was the Company's core product. ¶¶ 3, 43. Ampligen was co-invented by Defendant Carter in the 1970s

[5] Defendants argue that because Plaintiffs have not established an underlying violation of Section 10(b), the Section 20(a) claim must also fail, but they did not contest that the Individual Defendants are "controlling persons" of Hemispherx. Therefore, if the Court concludes that Plaintiffs have alleged a claim for securities fraud under Section 10(b), the Section 20(a) claim automatically survives. Defendants do not challenge the sufficiency of Plaintiffs' allegations of economic loss or loss causation.

and later was licensed to Hemispherx. Since its invention, ***Ampligen has been a drug in search of a disease***. ¶ 29.

**A. Background Regarding the Ampligen New Drug Application**

For more than two decades, Hemispherx has sought marketing approval for Ampligen for everything from chronic hepatitis B, to smallpox, HIV, Ebola, avian flu, and even the H1N1 virus. *Id*. In the late 1980s, Ampligen flunked its clinical trial for treatment of HIV – a fiasco that temporarily cost Defendant Carter his job as Hemispherx's CEO. ¶ 31. By 1990, Defendant Carter had returned as CEO and Hemispherx had switched its focus to CFS – a poorly understood syndrome with no known cause that starts with flu-like symptoms and progresses to chronic weakness and fatigue. ¶¶ 31, 34. Since there is no laboratory test for CFS, diagnosis can only be made by ruling out all other known causes for the patient's symptoms. ¶ 32.

Hemispherx filed an application for a "treatment IND" for Ampligen on September 3, 1991, based on the results of a study involving 92 patients with CFS.[6] ¶ 34. In October 1991, the FDA notified the Company that it was placing the application on hold, as the data, which the FDA considered inadequate to assess the safety and effectiveness of the drug, did not support the expansion of Ampligen treatment. ¶ 35. At the time, the FDA also raised serious concerns about potentially life-threatening reactions to Ampligen, including acute liver toxicity, severe abdominal pain and irregular heartbeat that were observed during the study. *Id*. In October 1992, Hemispherx was authorized by the FDA to begin a Phase II study of Ampligen for the treatment of CFS. *Id*. In 1994, the results of the Phase II study of Ampligen in CFS patients were published ("AMP 502"). ¶ 36. According to the Company, patients treated with Ampligen

[6] A "treatment IND" status is intended to provide desperately ill patients with experimental drugs even before they are approved for marketing. Treatment IND status is given to drugs completing Phase II or currently in Phase III trials. ¶ 34.

reported a "clinically significant" improvement in their functional impairment (the primary endpoint of the study[7]) compared to placebo, as measured by the Karnofsky Performance Scale, which measures functional performance. Based on this study, Hemispherx pushed Ampligen into a larger, Phase III study. *Id*.

The Phase III clinical trial ("AMP 516") began enrolling patients in 1998. ¶ 37. The study used the same dose of Ampligen as the Phase II study, but extended the treatment from 24 to 40 weeks and changed the primary endpoint to improvement in treadmill exercise tolerance. *Id*. In a May 3, 2006 press release, Hemispherx reported, "that the tests achieved improvements far above the levels considered medically significant."[8] However, the results of the "intent to treat analysis," which is the analysis that the FDA considers relevant because it counts the results for all of the patients enrolled in the trial (including those who did not complete the trial), were not statistically significant. *Id*. Specifically, Hemispherx's December 12, 2006 press release, issued more than two years before the beginning of the Class Period, stated: "In the completed Phase 3 trial, patients receiving Ampligen® for 40 weeks improved exercise treadmill performance 14.8% in the placebo group (p=0.025) and 13% by the intent to treat analysis (p=0.052)." Def. Appendix Ex. 16. Because the statistical p-value for the intent to treat analysis in the Phase III trial was p=0.052, which is higher than p=0.05, it was not statistically significant and did not meet FDA statistical standards. ¶ 37.

[7] The "primary endpoint" of a clinical study refers to the end-results of the primary objective or hypothesis of the study, and is viewed as an indicator of a given treatment's efficacy.

[8] Hemispherx press release entitled, "Hemispherx Biopharma to Present Audited Results of Ampligen® Clinical Trials on Chronic Fatigue Syndrome at 5th International Conference on HHV; Studies Show Medically Significant Improvements Among CFS Patients," (May 3, 2006), Def`. Appendix Ex. 15.

Hemispherx finally filed its NDA for Ampligen with the FDA on October 10, 2007. ¶ 38. On December 3, 2007, Hemispherx received a Refusal to File notice from the FDA because its NDA filing was deemed "not substantially complete."[9] *Id*. Hemispherx filed amendments to its Ampligen NDA on April 25, 2008, and on July 7, 2008, the FDA accepted the NDA for review as a treatment for CFS.[10] *Id*. Defendants reported that a response from the FDA was set for February 25, 2009, according to the requirements of PDUFA.[11] ¶ 39.

**1. Defendants Bet the Company on Ampligen – Its Core Product**

Defendants acknowledge in Hemispherx's SEC filings, including each of its quarterly reports on Forms 10-Q during the Class Period that Ampligen is its core product and that the Company's "strategic focus is . . . our two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®." ¶ 43. Moreover, during the Class Period, obtaining FDA approval for the Ampligen NDA was the Company's most important project. ¶ 43. As Defendants stated in Hemispherx's Form 10-K filed with the SEC on March 9, 2009, obtaining approval of the

[9] According to the Company's Form 8-K filed on December, 7, 2007, the NDA "had been determined to be insufficiently complete to permit a substantive review under 21 CFR § 314.101(d). Specifically, eleven deficiencies were noted in the Clinical Section and three in the Pre-Clinical Section." Def. Appendix Ex. 18. Pursuant to 21 CFR § 314.101(d)(3), the FDA may refuse to file an NDA when the "application or abbreviated application is incomplete because it does not on its face contain information required under section 505(b), section 505(j), or section 507 of the act and 314.50 or 314.94." *New Drug Evaluation Guidance Document: Refusal To File* (July 12, 1993), Def. Appendix Ex. 81. The FDA enacted this regulation to combat the practice of submitting incomplete or inadequate applications and then "repairing" them over the course of a prolonged review period, because this practice is inherently inefficient and wasteful of agency resources. *Id.*

[10] In the interim between the initial submission of the NDA and the filing of the amended NDA, on January 9, 2008, Hemispherx issued a press release announcing that it had responded to all fourteen of the questions posed by the FDA concerning the NDA. Def. Appendix Ex. 19. On March 6, 2008, the Company issued a press release stating that, following a face-to-face meeting with the FDA, "the number of items necessary to accomplish a complete NDA . . . has been reduced from an original fourteen (14) to five (5)." Def. Appendix Ex. 20. At that time, Hemispherx reported that "no further studies are required to achieve a complete NDA filing . . . ." *Id*. Then, on May 13, 2008, the Company issued a press release stating that "the five remaining filing related issues have now been addressed by the Company's filing of amendments to its NDA on April 25, 2008." Def. Appendix Ex. 21.

[11] The so-called "PDUFA clock" starts on the day the NDA is filed with the FDA. Thereafter, the FDA has up to six months to issue an approval decision. Drug firms typically issue press releases when they file an NDA so that investors can calculate the date by which the FDA must issue its decision, referred to as the "PDUFA date." ¶ 27.

Ampligen NDA was one of the Company's primary objectives: "[W]e have reviewed every aspect of our operations for cost and spending reductions to assure the long-term survival of our Company ***while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® . . . .***" ¶42 (emphasis added). Indeed, Defendants essentially bet the Company on the Ampligen NDA. ¶ 40.

As a result of the Company's decades long pursuit of FDA approval of Ampligen, Hemispherx has been a company in desperate need of cash. *Id*. Since 1987, Hemispherx has incurred substantial operating losses due to its research and development programs, the most significant of which is Ampligen. *Id*. The Company derives revenue only from the Ampligen cost recovery program and commercial sales of Alferon Injection – a drug approved for the limited purpose of treating refractory genital warts.[12] ¶¶ 40-41. As of March 31, 2009, the Company reported that it had "not yet generated significant revenues from [its] products," and had an accumulated deficit of ***more than $200 million***. ¶ 41. Hemispherx ran up this massive deficit by throwing all of its resources into the development of Ampligen.

For example, the Company disclosed in its Form 10-K filed with the SEC on March 9, 2009, that it had burned through $9,358,000 "reflecting mainly expenditures for the preparation and filing of the Ampligen(R) NDA" for the year ended December 31, 2008. ¶ 42. Likewise, for the year ended December 31, 2008, Hemispherx had a net loss of more than $12.2 million or $0.16 per share.[13] As a result, by February 28, 2009 (roughly the beginning of the Class Period),

[12] The Company actually ceased selling Alferon during the Class Period because it chose not to spend its limited funds on manufacturing Alferon. ¶ 3. *See also* Def. Appendix Ex. 7, 3Q 2008 Form 10-Q at 17 ("Production of Alferon N injection® . . . has been put on hold at this time due to resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen® NDA. Work on the Alferon N Injection® is expected to resume in mid-2009 under the condition that adequate funding is obtained . . . .")

[13] *See* Def. Appendix Ex. 27.

Hemispherx's cash, cash equivalents and short-term investments had dwindled to approximately $5,734,000. ¶ 42. Hemispherx continued to post abysmal financial results throughout the Class Period, including a net loss of $3,087,000 or $0.04 per share for the first quarter of 2009, when the Company burned through $1,434,000 for operating activities;[14] a net loss of $3,870,000 or $0.04 per share for the second quarter of 2009;[15] and a net loss of $2,435,000 or $0.02 per share for the third quarter of 2009.[16]

Because the Company had no source of substantial near term revenues, and its financial condition was so poor, it resorted to paying a portion of the salaries and fees of its Board of Directors, employees, consultants and vendors in stock.[17] ¶ 6. Moreover, as Hemispherx disclosed in a November 28, 2008 press release, the Company was forced to drop its product liability insurance for Ampligen and Alferon N in order to save its dwindling cash reserves. *See* November 28, 2008 Press Release, Plaintiff's Exhibit A ("Additional cost reduction measures include suspending product liability insurance for Alferon™ N and Ampligen® until the Company receives regulatory clearance for Ampligen® and requiring third parties to indemnify the Company in conjunction with all overseas compassionate sales of Ampligen® and Alferon™ LDO.")[18] In fact, the Company's financial condition was so dire that Defendant Carter agreed to enter into a standby financing agreement ("Standby Financing Agreement") with Hemispherx, in which he agreed to loan the Company up to $1,000,000 of his personal funds to maintain the

[14] *See* Def. Appendix Ex. 31.

[15] *See* Def. Appendix Ex. 46.

[16] *See* Def. Appendix Ex. 59.

[17] *See also* Def. Appendix Ex. 91, at 12 ("[W]e've instituted company-wide an internal program of issuing restricted stock to staff members as well as certain vendors to conserve our cash resources . . . .")

[18] "As a cash conservation measure," the Company also dropped its "Key Man" life insurance policy for $2 million on Defendant Carter "until we receive regulatory clearance for Ampligen." ¶ 87.

Company's operations should it be unable to obtain alternate financing through securities offerings or external financing agreements. ¶ 83. Therefore, Hemispherx's very survival – much less its ambitious plans for Ampligen – were dependent on its ability to conduct one or more offerings of its stock, which rested upon a market belief that its FDA application would be approved without substantial delay. ¶ 6.

With these massive losses and growing deficit as a backdrop, Defendants emphasized the commercial potential of Ampligen during the Class Period. For example, Defendant Carter stated during a March 1, 2009 analyst call that "[a] drug in this class would certainly have the potential to be a ***$1 billion product*** assuming that it was accepted in the marketplace. . . ." ¶ 45. Defendant Carter highlighted the market's lack of any drug approved for CFS treatment, and declared that Ampligen would be the first and only drug therapy available for CFS treatment if approved by the FDA. ¶ 44.

On May 8, 2009 and May 18, 2009, Hemispherx entered into two securities purchase agreements with institutional investors through which Defendants raised in the aggregate approximately $33.7 million for the Company. ¶¶ 61, 63-64, 84. On July 2, 2009, the Company entered into a common stock purchase agreement with another institutional investor through which Defendants raised an additional $28.1 million for the Company. ¶ 84. Together, these Class Period securities offerings raised more than $61.8 million, and allowed the Company to embark on a grandiose plan to manufacture massive quantities of Alpheron LDO and Ampligen for investigation and possible clinical trials as flu vaccine adjuvants – a project that Defendant Carter stated in the July 22, 2009 conference call would require a $10 million investment. ¶ 85.

By hyping the commercial potential for Ampligen and making the false and misleading statements and material omissions set forth in detail below, Defendants were able to artificially

inflate the price of Hemispherx common stock during the Class Period from $0.32 per share on the first day of the Class Period, to $1.38 per share on May 8, 2009, when Hemispherx conducted its first securities offering of the Class Period, and to $1.93 per share on May 18, 2009, when the Company completed its second securities offering of the Class Period. *See* Hemispherx Stock Price Chart, Plaintiff's Exhibit B. By July 2, 2009, when Hemispherx completed its third securities offering of the Class Period, the price of the Company's stock had rocketed to $2.54 per share. *Id.*

**B. Defendants' False and Misleading Statements During the Class Period**

On November 2, 2009, Defendants revealed that their Class Period statements that they had "***answered all the major questions that have been put forward with the Agency***," and that "***the major questions which [the FDA] have asked have in our opinion been retired***," ¶ 52, as well as their statements concerning the reasons for the delays of the PDUFA date, were materially misleading. Specifically, the Company's November 2, 2009 press release admitted:

> However, ***several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay*** as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and September 15, 2009, the Company issued six (6) ***new*** reports to the Agency spanning various subjects including: (i) clinical safety assessments, (ii) specialized pre-clinical toxicology reports, and (iii) abbreviated chemistry and manufacturing control reports.

¶ 75 (emphasis added). Defendants further admitted that Hemispherx would be submitting four ***additional*** reports in November and December 2009, including "pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) . . . ." *Id*. (emphasis added). Thus, numerous ongoing FDA inquires and the required submission of ***ten new reports*** were the cause of the delays in the FDA's review of the Ampligen NDA – not the FDA's workload, as Defendants led investors to believe.

Defendants' false and misleading statements and material omissions fall into two general categories. The first category involves misrepresentations regarding the reasons for the delays of the PDUFA date, which Defendants falsely attributed to the FDA's workload and its implementation of new regulations, while deliberately or recklessly concealing the fact that, throughout the Class Period, the Company was responding to FDA requests for additional information and working on new reports on various topics to which the Company needed to respond before the FDA would complete its review of the Ampligen NDA. The second category involves misrepresentations that: (i) statistically significant results of Ampligen's Phase III clinical trials (a prerequisite for FDA approval of an NDA) had established the safety and efficacy of Ampligen; (ii) the Company had performed adequate testing to prove that the drug did not cause dangerous cardiac side effects; and (iii) sufficient carcinogenicity testing of the drug had already been performed, and thus, a waiver of further cancer testing was warranted.

### C. Defendants' Scienter for Misstatements Concerning Delays of the PDUFA Date

Defendants were highly motivated to misrepresent the reasons for the delays of the PDUFA date, in order to artificially boost the prices of Hemispherx common stock and thereby cause investors to pour more than $61.8 million into the Company during the Class Period. Such funds would not have been forthcoming if Defendants had been truthful about the Ampligen NDA. ¶ 84. Defendant Carter himself was motivated to mislead investors so that Hemispherx could raise money through Class Period securities offerings, thereby allowing him to avoid his personal obligation to finance the Company's operations pursuant to the February 2009 Standby Financing Agreement, in which he agreed to loan the Company up to $1,000,000 if it was unable to obtain other financing. ¶ 83.

Defendants Carter and Strayer were each personally motivated to make misstatements concerning reasons for delays of the PDUFA date to receive large incentive-based cash bonuses and stock-based awards. ¶ 104. Specifically, as detailed in a report on Form 8-K filed with the SEC on May 27, 2009, Defendant Carter caused himself to be awarded $300,000 and Defendant Strayer to be awarded $150,000 for simply having the FDA accept the Ampligen NDA for filing and for raising desperately needed cash. *Id*. Additionally, a February 10, 2010 press release revealed that Defendant Carter, acting in his role as Chairman of the Board of Directors, saw fit to siphon off a portion of the cash raised in the Company's Class Period securities offerings to pay himself a $182,772 year-end bonus for 2009 and Defendant Strayer a $44,306 year-end bonus for 2009, despite the FDA's denial of the Ampligen NDA. ¶ 105.

Defendant Carter had actual knowledge of the FDA's requests for additional reports during the Class Period and the reasons for the delays of the PDUFA date, as evidenced by statements of a former Hemispherx employee that all of the Company's communications with the FDA went directly through Defendant Carter. ¶ 86. Specifically, the former Hemispherx employee who worked at the Company's headquarters from 1999 through the end of 2008 (which includes the time period in which Hemispherx filed its Ampligen NDA) and worked closely with Defendant Carter in an administrative capacity, stated "[t]hat Dr. Carter tightly controlled the communication channel between Hemispherx and the FDA was an understatement. Everything went through him or not at all." *Id*. This former employee also said, "Dr. Carter did not want any of the information that was going back and forth to the FDA regarding Ampligen to get out into public knowledge until he wanted it to get out." *Id*.

The fact that Defendant Carter controlled all communications with the FDA is corroborated by two letters from the FDA in which the agency reprimanded Defendants, and in

particular Defendant Carter, for improperly making statements promoting Ampligen as a safe and effective drug for treatment of CFS prior to receiving marketing approval from the FDA. ¶ 113. Specifically, Defendants were notified by the FDA of these violations of federal law by letters addressed directly to Defendant Carter dated October 15, 1998 and July 7, 2000. ¶¶ 113-114. The fact that the FDA was directly communicating with Defendant Carter, rather than a lower level employee, in these letters establishes Defendant Carter's hands-on participation in the FDA application process and his control over the Company's communications with the agency. ¶ 115.

Evidence of Defendants Carter's and Strayer's knowledge about the FDA's requests for additional reports that delayed the PDUFA date is further supported by their extensive, frequent and detailed discussions concerning the Ampligen NDA during Hemispherx's investor conference calls, both before and during the Class Period, including calls on December 19, 2007, April 9, 2008, July 17, 2008, March 19, 2009, June 12, 2009, July 22, 2009, October 9, 2009, as well as Defendant Strayer's presentation at the IACFS/ME 9th International Research and Clinical conference on March 12-15, 2009. ¶¶ 51-52, 54-56, 59, 66, 68, 71, 97-103. Indeed, the topic of the Ampligen NDA dominated Defendant Carter's and Strayer's discussions during these conference calls. *Id*.

Defendant Carter's actual knowledge of the Company's activities, including its clinical trials, is admitted in Hemispherx's Form 10-Q filed with the SEC on November 9, 2009, which states:

> Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs***, his being the co-inventor of Ampligen®, and his knowledge of our overall activities, including patents and clinical trials.*** The loss of the services of personnel key to

> our operations or Dr. Carter could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance in the amount of $2,000,000 on the life of Dr. Carter until we receive regulatory clearance for Ampligen®.

¶ 87 (emphasis added).

### D. Defendants' Scienter for Misstatements Concerning Safety and Efficacy of Ampligen

Defendant Carter's scienter for his false statements concerning the safety and efficacy of Ampligen is supported by, among other things, his admission during the December 3, 2009 conference call that the FDA's request for an additional third clinical trial was not unexpected because the FDA had required a similar study in the case of Pfizer's Lyrica, a drug for Fibromyalgia (a disease with significant overlap with CFS). ¶ 88. Specifically, Defendant Carter stated:

> ***Now a bit about the history of Chronic Fatigue Syndrome and a related disease, which is called fibromyalgia syndrome, FMS. These are two sister diseases, which have about a 20% overlap. By that I mean, you can meet the diagnostic criteria for either disease with the same symptoms in about 20% of the patients.***
>
> You may remember that the pioneering company in fibromyalgia has been Pfizer in a product called Lyrica. A couple of years ago, notwithstanding the fact that they had two well-controlled studies, ***Pfizer was requested by the agency as a preapproval requirement to conduct a third study.*** You can confirm this by looking in the package insert.
>
> In the instance of Lyrica in fibromyalgia they were able to use the treatment IND patients and basically wean them off-drug and look at the response pattern. ***So there are significant historical analogies here between the fibromyalgia successes and what we believe may be the successes with Chronic Fatigue Syndrome.***
>
> ***A third trial is not unexpected in a situation where you're dealing with a large disease category, in this case these diseases may have as many as 4 million***

> ***subjects. And of course there are no – there were no drugs on the market for fibromyalgia until Lyrica***, and in the case of Chronic Fatigue Syndrome, obviously there are no other drugs on the market, and indeed Ampligen is the only product, which has the emergency treatment IND provision.

*Id*.

Defendant Carter had recognized the similarities between the Lyrica NDA and Hemispherx's Ampligen NDA at least as early as April 2008, and thus knew of, or recklessly disregarded, that a third clinical trial, like the one required for Lyrica, would be needed for Ampligen. ¶ 89. Yet Defendant Carter represented in an April 9, 2008 conference call that additional studies would not be needed to obtain FDA approval, stating: "[W]e do not believe any additional studies will be needed to complete the NDA filing status presumptively to go forward with a total application and receive a favorable review." ¶ 90. Despite highlighting the similarities between the Ampligen NDA and Pfizer's successful application for Lyrica, a drug for Fibromyalgia, *id*., Defendants nevertheless did not perform a third clinical trial, knowing that this failure would likely jeopardize the chance for first cycle FDA approval of the Ampligen NDA.

**E. <u>The Truth Finally Emerges</u>**

On November 2, 2009, Defendants finally disclosed that the reason for the delays in the PDUFA date was that the Company had been actively engaged in responding to numerous FDA inquiries since March 2009. The Company issued a press release on November 2, 2009, entitled: "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS); Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS," which stated:

> The Company also plans to complete all outstanding queries from the FDA regarding its New Drug Application (NDA) for Ampligen®, an experimental

> therapeutic, during November and December, 2009. On May 26, 2009, the Company announced a delay on the Ampligen NDA which, at the time, had a PDUFA date of May 25, 2009. As noted in the 10-Q and 10-K filings at the time, the FDA did not request additional information from the Company at that time. However, ***several outstanding NDA items, requiring Hemispherx responses, existed at the time of the FDA delay as noted in the August 8, 2009, 10-Q filing. Between March 9, 2009 and September 15, 2009, the Company issued six (6) new reports to the Agency spanning various subjects including a) clinical safety assessments, b) specialized pre-clinical toxicology reports, and c) abbreviated chemistry and manufacturing control reports.*** The Company believes that these reports may fully retire all agency queries in these particular areas.
>
> ***The company also plans to submit four (4) additional reports on interrelated topics in November and December, 2009***, which will include pharmacokinetic analyses in multiple lower animal species (primates, rodents, etc.) ("the Lovelace Laboratory Studies") and final validation reports of certain manufacturing procedures conducted at an independent facility, Hollister-Stier Laboratories in Spokane, WA. Some of these reports were recently cited in BioMedReports.com and the Science Business Exchange (October 15, 2009).

¶ 11 (emphasis added).

As a result of the November 2, 2009 disclosure of facts that had previously been concealed, the price of Hemispherx common stock plummeted from $1.45 per share on October 30, 2009, to close at $1.33 per share on November 2, 2009 (an 8.28% decline) on unusually heavy volume of 2,409,294 shares traded; and declined further on November 3, 2009, when it closed at $1.13 per share (a 15.04% decline), on unusually heavy volume of 8,739,506 shares traded. ¶¶ 12, 122. In contrast to the sharp decline in the price of Hemispherx common stock on November 2 and 3, 2009, two comparable market indices, the AMEX Biotech Stock Index ("BTK") and the NASDAQ Biotech Stock Index ("NBI"), actually increased in value on November 2, 2009 by 2.92% for BTK and by 0.52% for NBI, with even larger increases over the two day period ending on November 3, 2009 (6.48% for BTK and 2.45% for NBI). ¶ 123.

The financial press was highly critical of Hemispherx following the November 2, 2009 disclosures. For instance, on November 3, 2009, *TheStreet.com* published an article entitled "Hemispherx Cops to Ampligen FDA Delay," which stated in part:

> Hemispherx Biopharma issued an "update" to the regulatory status of its chronic fatigue syndrome drug Ampligen in which ***the Company essentially admits that its prior public statements were false and misleading***.
>
> Monday's statement was likely crafted by Hemispherx's lawyers as a way to help CEO Carter wiggle out of public statements he made in May and June claiming the Ampligen application to the U.S. Food and Drug Administration was to be complete. ***Carter insisted regulators weren't asking for any additional information on Ampligen.***
>
> Carter made these statements both before and immediately after the FDA approval decision date for Ampligen on May 25, which came and went without any word from the agency. ***We now know that Carter's statements were demonstrably false. The FDA application for Ampligen was not complete because several items were outstanding, the Company now states.*** These included FDA requests for data on Ampligen's safety both in humans and animals. The FDA also required additional information about Ampligen's manufacturing.

¶ 75 (emphasis added).

On December 1, 2009, after the market closed, the Company issued a press release revealing that the FDA had advised the Company in a Complete Response Letter that the Ampligen NDA could not be approved because, among other reasons, the clinical studies submitted with the application "did not provide evidence of efficacy of Ampligen," a finding which was substantially based on the fact that the results for the "intent to treat" analysis of the primary endpoint of the Phase III trial were not statistically significant. ¶¶ 13, 124. The December 1, 2009 press release disclosed that as a result, the Company could not hope to obtain approval of Ampligen without conducting at least one additional large human study "which shows a convincing effect and confirms safety in the target population," and that the new study

would need to provide evidence of cardiac safety. *Id*. Moreover, Defendants admitted that the FDA "is recommending that the Company complete rodent carcinogenicity studies in two species," which the Company had chosen not to perform, but instead asked the FDA to waive.

A December 2, 2009 article in *TheStreet.com* described the FDA action and its dire consequences for Hemispherx as follows:

> The regulatory agency's rejection of Ampligen is a staggering blow to Hemispherx, which has pursued the drug's development in a dizzying array of diseases for more than 20 years with no success.
>
> Hemispherx shares plunged 43% to 68 cents in early Wednesday trading.
>
> ***The FDA's complete response letter to Hemispherx – summarized in the company's Tuesday night press release – essentially instructs Hemispherx to start Ampligen's clinical trial program from scratch.***
>
> ***The agency's medical reviewers concluded that the two clinical studies of Ampligen submitted by Hemispherx "did not provide credible evidence of efficacy," according to the company.***
>
> In order to reconsider Ampligen for review, the FDA instructed Hemispherx to conduct at least one additional clinical study in chronic fatigue syndrome. The study needs to test different doses of Ampligen for a minimum of six months, including at least 300 patients on Ampligen dose regimens intended for marketing, according to Hemispherx's summation of the FDA's letter.
>
> * * *
>
> ***But the FDA is asking for even more from Hemispherx, including tests of Ampligen in rodents to rule out the risk of cancer and a safety study in humans to ensure that Ampligen doesn't cause dangerous changes to a patient's heart rhythm.***

¶ 80.

As a result of the foregoing disclosures in the December 1, 2009 press release, the market price of Hemispherx common stock plunged an additional $0.49 per share, from a closing price of $1.20 per share on December 1, 2009 to close at $0.71 per share on December 2, 2009, a decline of 40.83%, on unusually heavy volume of 26,168,813 shares traded; and declined further

on December 3, 2009, when it closed at $0.68 per share (a 4.23% decline), on unusually heavy volume of 7,510,378 shares traded. ¶¶ 14, 125. In contrast to the sharp decline in the price of Hemispherx common stock on December 2 and 3, 2009, both the BTK index and the NBI index actually increased in value on December 2, 2009 by 1.19% for BTK and by 0.89% for NBI, and over the two day period ending on December 3, 2009, the BTK increased by 0.83% and the NBI fell slightly by 0.13%. ¶ 126.

## III. ARGUMENT

### A. Summary of Argument

The vast majority of Defendants' brief raises arguments which are inappropriate at this stage in litigation. A Rule 12(b)(6) motion is not a vehicle to resolve factual disputes. A defendant may not obtain dismissal by contesting the allegations of the Complaint and seeking to have the Court adopt its version of the facts. *See, e.g., Jackson v. Rohm & Haas Co.*, No. 06-3682, 2007 U.S. Dist. LEXIS 71858, at * 4 (E.D. Pa. Sept. 26, 2007) (deciding issue of fact inappropriate for motion to dismiss); *Freedom Med., Inc. v. Gillespie*, No. 06-3195, 2007 U.S. Dist. LEXIS 63720, at *71 (E.D. Pa. Aug. 29, 2007) (same); *Novunger Group, Inc. v. Hartford Ins., Inc.*, No. 1:06-cv-0188, 2007 U.S. Dist. LEXIS 35779, at *28 (E.D. Pa. May 16, 2007) (same). "[F]aced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, by asserting numerous defenses that courts regularly find are premature at the motion to dismiss phase, Defendants have inevitably created questions of fact, which require denial of their motion.

Defendants set forth their version of the "facts" over a rambling forty pages, including "ancient history" from long before the Class Period. Many of Defendants' facts directly contradict facts pled in the Complaint and therefore cannot be considered at the motion to dismiss phase. *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1995) (reversing dismissal of claim because lower court "chos[e] to believe" contentions set forth in defendant's affidavit, thereby "fail[ing] to take the allegations in the complaint as true – as it must in considering a motion to dismiss under Rule 12(b)(6)"); *Yamrus v. Township of Washington*, No. 08-2842, 2009 U.S. Dist. LEXIS 43255, at *7 (E.D. Pa. May 20, 2009) (holding that "[w]hile defendants' motion to dismiss disputes . . . facts, such factual disputes are matters for juries to decide").[19]

The bulk of Defendants' legal challenges to Plaintiffs' allegations of false and misleading statements amounts to a "truth-on-the-market" defense, which is improperly raised at this stage of the litigation. What the market knew and whether investors were deceived by Defendants' statements are factual issues. For example, Defendants contend that "Dr. Carter repeatedly and publicly stated that Hemispherx was continuing to submit reports to the FDA," thereby implying that the market knew the reason for the FDA delay. Def. Br. at 56. In arguing that the

[19] One example illustrates Defendants' improper tactics. The Complaint cites an article dated November 3, 2009 published in *TheStreet.com*, which is a blog published on the *Wall Street Journal's* website. ¶ 75. The article was cited not only to show that prior statements made by Defendants were false, but also to demonstrate the investing public's reaction to Defendants' November 2, 2009 revelations that the reason for the FDA's delay was the required submission of ten new reports from Hemispherx – not due to FDA staffing issues. ¶ 73. Rather than accept the allegations at face value, as they are required to do in addressing the *legal* sufficiency of the Complaint, Defendants attempt to attack the credibility of the author and the veracity of his statements. Def. Br. at 3-4. Defendants declare that the author, Adam Feuerstein, "falsely accuse[d]" Defendants of "lying to investors about the status of the Ampligen NDA and falsely suggest[ed] that the Company's NDA had not in fact been accepted for review by the FDA." *Id.* Defendants later assert that Mr. Fuerstein's article contained "speculative rantings" and that his opinions "lack credibility." Def. Br. at 73 n. 63. However, witness credibility determinations are reserved for the fact-finder, and are not considered fodder for a summary judgment motion, much less for a motion to dismiss. *Prime Building Corp. v. Itron, Inc.*, 22 F. Supp. 2d 440, 445 (E.D. Pa. 1998) (holding that credibility disputes are "not appropriately resolved at the summary judgment stage"); *Gerber v. Meisel*, Civ. A. No. 02-7650, 2003 U.S. Dist. LEXIS 20797, at *7 (E.D. Pa. Nov. 13, 2003 (holding that "[i]t should be left to the trier of fact to weigh the credibility of each witness and to determine whose version of the events to credit"). Moreover, Plaintiffs offered the article primarily as an example of the *reaction of reasonable investors* who were misled by Defendants' Class Period statements.

Complaint does not plead material omissions and misstatements, Defendants do not dispute the falsity of the alleged statements, but instead claim that "defendants, in fact, ***did*** disclose this information – promptly, fully and repeatedly – both before and during the Class Period." Def. Br. at 50.

Defendants' truth-on-the-market defense must be rejected because they face a "heavy burden of proof" to show that "no rational jury could find that the market was misled." *See Provenz v. Miller*, 102 F.3d 1478, 1492-93 (9th Cir. 1996). Furthermore, they are not permitted to assert the truth-on-the-market defense at the motion to dismiss phase because such an inquiry is highly-fact intensive and therefore only appropriate for a fact-finder. *Basic v. Levinson*, 485 U.S. 224, 249 n. 29 (1988); *Saddle Rock Partners, Ltd. v. Hiatt*, No. 95-2326, 1996 U.S. Dist. LEXIS 20649, at *53 (W.D. Tenn. March 26, 1996).[20]

Defendants also argue that certain of the misstatements were mere "puffery," (Def. Br. at 66-68), *i.e.*, that the misstatements were immaterial. *See EP Medsystems, Inc. v. Echocath, Inc.*, 235 F.3d 865, 872 (3d Cir. 2000) (contrasting "[m]aterial representations" with statements of puffery). Like the truth-on-the-market defense, questions as to materiality are generally not

[20] Defendants' truth-on-the-market defense fails for at least two additional reasons. *First* as explained more fully in Section III.D.2, *infra*, they have not come close to showing that the so-called public information they cite "effectively counterbalanced" their false and misleading statements. *See Saddle Rock Partners, Ltd.*, U.S. Dist. LEXIS 20649, at *53; *DeMarco v. Robertson Stephens Inc.*, 318 F. Supp. 2d 110 (S.D.N.Y. 2004). *Second*, the entire premise of the truth-on-the-market doctrine is that "the market has become aware of the allegedly concealed information," and therefore "the facts allegedly omitted by the defendant would *already be reflected in the stock's price*." *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996); *see also Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 516 (7th Cir. 1989) ("Prompt incorporation of news into stock price is the foundation for the fraud on the market doctrine and therefore supports a truth on the market doctrine as well."). In this case, Defendants cannot seriously assert that the information concerning the real reasons for delay at the FDA was known by the market throughout the Class Period. When those reasons were revealed, the price of Hemispherx's stock declined by 23% on November 2 and 3, 2009 (¶¶ 12, 73-75, 122), and by an additional 44% on December 2 and 3, 2009. ¶¶ 14, 77-78, 125. The materiality of information may be evidenced by movement in a company's stock price following disclosure. *See In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 544 (D.N.J. 2002) ("'when a stock is traded in an efficient market, the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following the disclosure, of the price of the firm's stock'"); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1425 (3d Cir. 1997) ("In the context of an 'efficient' market, the concept of materiality translates into information that alters the price of the firm's stock.").

decided on a Rule 12(b)(6) motion, but instead "require[] delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him, and these assessments are peculiarly ones for the trier of fact." *TSC Indus. Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1975); *see also RMED Int'l Inc. v. Sloan's Supermarkets, Inc.*, 185 F. Supp. 2d 389, 400 (S.D.N.Y. 2000) (observing the Supreme Court's belief that "materiality is particularly well suited for jury determination"); *Feiner v. SS&C Techs.*, 11 F. Supp. 2d 204, 207-08 (D. Conn. 1998) (refusing to dismiss claim because alleged misstatements and omissions could not be determined immaterial as a matter of law, and noting that "it is unlikely that a cause of action which requires a determination of materiality can be dismissed as a matter of law"). More importantly, Defendants have taken the four statements they challenge as puffery out of context. As discussed in detail in Section III.G., *infra*, these four statements fairly considered in context are material, non-puffery.

Defendants argue that their misstatements were forward-looking, and are therefore entitled to the safe harbor protections of the PSLRA. However, in order to qualify for such protection, Defendants must demonstrate that their statements are, in fact, forward-looking, and if so, are accompanied by "meaningful cautionary language," a determination that is seldom resolved at the motion to dismiss phase. *See In re Lucent Techs., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 557 (D.N.J. 2002) (holding that the question of whether purportedly "cautionary language" identified by Defendants is "sufficiently 'meaningful' raises fact issues that are improperly resolved" at the motion to dismiss phase). *See* Section III.F., *infra.*

Finally, the Complaint contains abundant allegations that support the strong inference that Defendants acted with scienter. Defendants' arguments to the contrary result from a blatant misreading of the Complaint's scienter allegations. Having sufficiently alleged Defendants'

scienter, pursuant to the Supreme Court's guidance in *Tellabs, Inc.* 551 U.S. at 322-23, the burden shifts to Defendants to demonstrate that the allegations give rise to an inference of nonculpable conduct that is *stronger* than the inference of scienter. *Id.* However, Defendants offer *no* competing inference, much less a *stronger* inference, to defeat the inference of scienter, which is supported by numerous allegations described in detail in Section III, H, *infra*.

**B. Legal Standard for a Rule 12(b)(6) Motion**

A motion to dismiss is defeated where the complaint alleges "enough factual matter (taken as true)" to suggest that a violation occurred, and "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (citation omitted). Therefore, a court's task in resolving a Rule 12(b)(6) motion is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case. *In re Ravisent Techs., Inc. Sec. Litig.*, No. 00-CV-1014, 2004 U.S. Dist. LEXIS 13255, at *9 (E.D. Pa. July 12, 2004); *see also Register v. PNC Fin. Servs. Group, Inc.*, 477 F.3d 56, 61 (3d Cir. 2007) (on a motion to dismiss, "'[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims'"). *Twombly* instructs courts to apply a "plausibility" standard of review under Fed. R. Civ. P. 12(b)(6). *Id*. at 553.[21]

**C. Standard for Violation of the Exchange Act**

A plaintiff states a claim under Section 10(b) of the Exchange Act and Rule 10b-5

[21] "[I]n a pre-discovery motion to dismiss, 'the rigorous standards for pleading securities fraud do not require a plaintiff to plead evidence.'" *Gerber v. Bowditch*, No. 05-10782-DPW, 2006 U.S. Dist. LEXIS 27552, at *26 (D. Mass. May 8, 2006); *see also Ravens v. Republic N.Y. Corp* Civ. A. No. 99-4981, 2002 U.S. Dist. LEXIS 12162, at *22 (E.D. Pa. April 24, 2002 ) ("The plaintiffs in securities fraud cases are not required to plead all of the evidence and proof thereunder supporting their claims."); *In re Unisys Corp. Sec. Litig.*, No. 99-5333, 2000 U.S. Dist. LEXIS 13500, at *10 (E.D. Pa. Sept. 21, 2000) ("[N]either the Reform Act nor Rule 9(b) requires plaintiffs to plead all of the evidence and proof thereunder supporting their claim.").

promulgated thereunder by alleging "a misstatement or an omission of material fact with scienter in connection with the purchase or the sale of a security upon which plaintiffs reasonably relied and plaintiff's [sic] reliance was the proximate cause of their injury." *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 251 (3d Cir. 2009) (citing *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007)).

In order to bring a private action pursuant to Section 10(b) of the Exchange Act and Rule 10b-5, Plaintiffs must allege the following elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to . . . as 'transaction causation'; (5) economic loss; and (6) 'loss causation,' *i.e.*, a causal connection between the material misrepresentation and the loss."[22] *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005).

Plaintiffs must satisfy the heightened pleading rules codified in the PSLRA. *Avaya*, 564 F.3d at 252. The PSLRA provides two distinct pleading requirements. First, under 15 U.S.C. § 78u-4(b)(1), the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Avaya*, 564 F.3d at 252-253 (quoting *Winer Family Trust*, 503 F.3d at 326 (footnote omitted) (construing 15 U.S.C. § 78u-4(b)(1)). Second, the complaint must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). *Avaya*, 564 F.3d at 253. Both provisions require facts to be pleaded "with particularity," and "[t]his ['particularity'] language echoes precisely Fed. R. Civ. P. 9(b)."

[22] Defendants' motion does not dispute that the following elements of the cause of action are properly pleaded: connection with the purchase or sale of a security, reliance, economic loss and loss causation.

*Avaya*, 564 F.3d at 253 (quoting *In re Advanta Sec. Litig*, 180 F.3d 525, 534 (3d Cir. 1999); *see* Fed. R. Civ. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake.")).

Although the PSLRA replaced Rule 9(b) as the pleading standard governing private securities class actions, *see Tellabs*, 551 U.S. at 319, Rule 9(b)'s particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u-4(b)(1) of] the PSLRA." *Avaya*, 564 F.3d at 253 (quoting *Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 85 n.5 (1st Cir. 2008); *see also Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1165 (9th Cir. 2009) ("[T]he inquiry into whether plaintiffs have pled falsity with the requisite particularity under the PSLRA is nearly identical to that under Federal Rule of Civil Procedure 9(b) . . . . ")). This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *Avaya*, 564 F.3d at 253 (quoting *Advanta*, 180 F.3d at 534 (internal quotation marks omitted)). Section 78u-4(b)(1) adds an additional requirement where "an allegation regarding [a defendant's] statement or omission is made on information and belief." 15 U.S.C. § 78u-4(b)(1). In those circumstances, plaintiffs must also "state with particularity all facts on which that belief is formed." *Id.* (quoting *Advanta*, 180 F.3d at 534). Thus, when allegations are made on information and belief, the complaint must state the allegations with factual particularity, and also describe the sources of information with particularity, providing the who, what, when, where and how of the sources, as well as the who, what, when, where and how of the information those sources convey. *Id.*

As discussed below, Plaintiffs' allegations of the falsity of Defendants' statements comply with the PSLRA's pleading requirements. The Complaint methodically lists the various statements at issue and specifies which Defendant made each one. ¶¶ 47, 49, 51-52, 54-56, 59,

61-62, 65-66, 68-69, 71. Plaintiffs also describe the exact reasons each statement is false and plead that such misstatements are material. ¶¶ 48, 50, 53, 57-58, 60, 65, 67, 70, 72, 75-76. *See In re RAIT Fin. Trust Sec. Litig.*, 2008 U.S. Dist. LEXIS 103549, at *52-55 (E.D. Pa. Dec. 22, 2008).

**D. The Complaint Sufficiently Alleges False and Misleading Statements**

**1. Defendants' Misstatements About Delays of the PDUFA Date**

On February 18, 2009, the first day of the Class Period, Hemispherx issued a press release disclosing that the PDUFA date for the Ampligen NDA had been extended by the FDA from February 25, 2009 to May 25, 2009 because "[a]dditional data were received by the FDA within 3 months of the user fee goal date." Def. Appendix Ex. 25. However, rather than truthfully reveal that numerous outstanding FDA queries still remained unanswered by the Company, concerning critical issues such as clinical safety assessments, specialized pre-clinical toxicology reports, and pharmacokinetic analyses in multiple animal species, Defendants falsely blamed FDA workload for delays in the PDUFA date, stating:

> ***Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act ("FDAAA") and FDA's Safety First/Safe Use initiatives, work priorities may change resulting in the Agency going past the customary PDUFA goal set for reviews of an application.***
>
> A decision was originally expected by February 25, 2009, for the Company's submission of its Ampligen® NDA . . . .The extended user fee goal date is now May 25th, 2009.

¶ 47 (emphasis added). Defendants' statements about the FDA's "increased workload related to the recently enacted and implemented FDA Amendments Act" were little more than a smokescreen designed to conceal that Defendants were in the midst of preparing ten additional reports on topics such as clinical safety, pre-clinical toxicology, and chemistry and

manufacturing controls requested by the FDA that precluded any possibility that the FDA would complete its review of the Ampligen NDA by February 25. ¶ 48.

Defendant Carter's statements in a February 22, 2009 interview, in which he discussed the data that the Company had submitted within 90 days of the PDUFA date, did not cure the misleading nature of Defendants' Class Period statements because, among other reasons, these statements concealed the fact that the FDA had requested data concerning Ampligen's cardiac side effects, as well as other data from Hemispherx.[23] Indeed, Defendant Carter's February 22, 2009 interview merely disclosed that the Company had re-analyzed very old EKG data (including data from the 502 study that was completed in 1994) and claimed that Ampligen allowed CFS patients to decrease use of other medications that may contribute to heart failure.[24] Specifically, Defendant Carter stated:

> In our new filing we examined a detailed analysis of over 1,000 sufferers with chronic fatigue syndrome and over 1,000 electrocardiograms, trying to look for long-term trends that might explain why these patients have a higher incidence, for example, of catastrophic heart disease. Why do they have heart attacks which kill them? Why do they have heart failure?
>
> And in the analysis of this long-term data, which has only been available to us really in the last month or so, we found important clues which we believe give new insight into the sudden death of patients with chronic fatigue syndrome.
>
> * * *
>
> And we believe that we have discovered an important new, new reason for this and that Ampligen may be able to mitigate some of these deaths. And that's going to be the basis of the presentation that will be made in a couple of weeks at the International Chronic Fatigue Syndrome meeting.
>
> * * *

[23] *See* Def. Appendix Ex. 92, at 8-9, 10-11.

[24] *Id*.

> Well, in general we have examined the major causes of death in chronic fatigue syndrome. And the major causes of death include heart failure, suicide and cancer.
>
> And we have looked back over our data, including the data from the earlier 502 study, which was a well controlled, placebo controlled study, as well as our more recent well controlled study, and we have reached certain information which, while we can't go into the details of it at this, today, prior to the conference, we can say that the patients with chronic fatigue syndrome, having so many severe symptoms, take many medications – for controlling the symptoms of the disease.
>
> And we have found that in the drug, in the group that takes Ampligen there is a reduction in these concomitant medications.
>
> Unfortunately, some of these medications which the patients are taking alter the electrocardiogram in such a way that it predisposes the person to heart failure or heart attack. And, fortunately, in the setting of taking Ampligen we were able to demonstrate that there is a statistically significant reduction in these drugs which are potentially very harmful to the patient and which potentially could be life-threatening.

*Id*. Defendant Carter gives the impression that this "new" data was submitted spontaneously by Hemispherx on its own initiative, when it is clear, based on the Company's December 2, 2009 disclosures that the FDA was requesting that the Company perform "***a safety study in humans to ensure that Ampligen doesn't cause dangerous changes to a patient's heart rhythm***." This "new" cardiac data was actually submitted by Defendants in response to an undisclosed FDA inquiry, making Defendant Carter's February 22 statements materially misleading because they created the impression that the Company had fully studied the cardiac risks of Ampligen and that the Company would not need to perform costly additional studies of Ampligen's cardiac safety that would delay FDA approval indefinitely.

Defendants reiterated these false and misleading statements in the Company's Form 10-K filed with the SEC on March 13, 2009, stating:

> In February 2009, the Company received a letter from the Federal Drug Administration ("FDA") indicating that their originally scheduled Prescription

> Drug User Fee Act ("PDUFA") date on the Ampligen® (Poly I:Poly C12U) New Drug Application ("NDA") would be extended by three months "in order to provide time for a full review of the submission." A decision from the FDA was originally expected by February 25, 2009. The extended PDUFA date for Ampligen® is now scheduled for May 25, 2009. ***Due to constraints at the FDA, specifically and including the increased workload related to the recently enacted and implemented FDA Amendments Act and Safety First/Safe Use initiatives, work priorities may change resulting in the agency going past the customary PDUFA goal date set for reviews of an NDA.***

¶ 49 (emphasis added). Thus, Defendants once again falsely blamed FDA workloads for the undisclosed FDA requests for numerous reports to which the Company was responding throughout the Class Period and which the Company would need to complete before the FDA could make a decision regarding the Ampligen NDA. ¶ 50.

On March 19, 2009, during the Company's fourth quarter 2008 earnings conference call with securities analysts and investors, Defendant Carter made the following statements:

> ***We believe that we have answered all the major questions that have been put forward with the Agency***. Now under federal law, they can continue to ask questions as long as they want.
>
> ***But we believe that the major questions which they have asked have in our opinion been retired***. Obviously, we are trying to anticipate questions that might come up in the future so that we can be prepared should there be further questions.

¶ 52 (emphasis added). These assurances led investors to believe that all pending "major" questions had been answered by the Company, and there were no "major" hurdles blocking the Company's path to approval of the Ampligen NDA. However, this was not the case because when Defendants made these statements, Hemispherx was actively engaged in responding to numerous ongoing FDA requests for additional information on topics such as clinical safety, specialized pre-clinical toxicology, and chemistry and manufacturing controls, which were required for FDA review of the NDA.

On May 26, 2009, the Company issued a press release announcing another delay of the PDUFA date and again falsely blamed FDA scheduling problems. Defendants further misled investors by assuring them that "the FDA did not request additional information from the Company ***at this time***," ¶ 65 (emphasis added), when in fact numerous FDA requests were then outstanding and Defendants were busy responding to them:

> Hemispherx Biopharma, Inc. today announces that the U.S. Food and Drug Administration ("FDA") has advised the Company that it may require up to 1-2 additional weeks to take action beyond the scheduled Prescription Drug User Fee Act action date of May 25, 2009 on the New Drug Application for Ampligen® . . . Reason for the possible delay was attributed by the Agency to certain staff scheduling changes which might (or might not) delay the report. Accordingly the Company's development plan for Ampligen® continues as described in the recently filed 10Q and 10K, as ***the FDA did not request additional information from the Company at this time***.

*Id*. (emphasis added).

On June 12, 2009, during a biomedreports.com interview, Defendant Carter made the following statements:

> **Interviewer:** First of all, let's talk about what everyone is talking about, which is the FDA decision, ***is it safe to say that we haven't heard anything from the FDA in regards to Ampligen?***
>
> **Dr. Carter:** ***Correct***.

¶ 66 (emphasis added). This statement was untrue and materially misleading because it led investors to believe that the FDA had been silent, when in fact the FDA had been in contact with Hemispherx and had made multiple inquiries to which Hemispherx was then actively responding. ¶ 67.

On a July 22, 2009 conference call with investors and analysts, Defendant Carter again stated that the delays in FDA action were the result of the agency being "overworked" and he flatly denied that the FDA was waiting for any documents from Hemispherx:

Mr. Welsh: Yes, I was wondering if there's any foreshadowing or new news of the FDA's approval of Ampligen?

Dr. Carter: . . . I gave a brief status report at the introduction to this conference call. ***We have not received any recent news from the agency.*** And as I pointed out earlier in a call, we have a number of initiatives in the CFS area which are not dependent upon that specific – that specific set of correspondences from the agency.

And so we're moving on these – we're moving on a whole series of initiatives with respect to clinical trials, market development, safety study reports.

In the past, we've issued some re-reports. ***Now we're issuing complete audited reports on a variety of safety issues that the agency has raised over several years; no – no new issues, but now we're retiring them through – we believe we're retiring them through more comprehensive reporting***. So this is all – this is all going forward.

And as you know from earlier conference calls, ***we believe the agency is substantially overworked at the moment with its new initiatives. It has new senior management.*** And we expect that sometime in the fall, perhaps sooner, we will be hearing from the – from the agency.

* * *

[Carter]: What we – what we're doing now, since since ***we believe that we've received the totality of significant questions and have retired them***, we're now creating the dossier for Canada and for selected European countries.

* * *

Steve Gold: Hi Good Morning. The last we heard – well, we heard from the FDA – there was a one- or two-week delay, and I heard you discuss the FDA earlier, at the beginning of the call. I want to get a little bit specific about that, if I may. That was about two – two months ago or so. Next, we heard you say that you're expecting – now you're expecting a response sometime in the fall. ***What do you attribute this tremendous delay to? And to say that the agency is overworked or overloaded, wouldn't it be reasonable for the company to request an update – an updated timeline from the FDA?***

* * *

[Carter]: So this is a – this is a – ***this is a common phenomenon with respect to the agency.*** And even though it is hiring several thousand new people under its recent congressional appropriation, it's going to take awhile to train them.

I don't – I don't want to suggest – and if I suggested it, that we are not in – we are not in correspondence with the agency, that would be correct. We are regularly

> providing reports to the agency to different reviewers and different areas; for example, in the area of preclinical toxicology. And so we are in correspondence.
>
> With respect to the question of – the definitive answer to our pending NDA, it's been our impression and that of – and that of our regulatory counsel that the agency knows that we are most eager to – to determine what their deliberations are. They were present at a meeting at the end of May as a member of the HHS committee.
>
> * * *
>
> [Carter]: And we feel that if the – the appropriate course of action is is to be responsive to any queries, shall we say, that are still out there, and that's what we've been doing, as I said, providing definitive documents, where, before, there was summary documents, which we felt retired the issue but was not necessarily the totally enriched document with schedules of numbers, et cetera, et cetera.
>
> * * *
>
> Steve Gold: One final question. ***Is the FDA currently awaiting any data or documents from Hemispherx that may be delaying this approval?***
>
> [Carter]: ***We don't think that there are any documents.*** It's always hard to understand materiality, but there were many, for example, many inspections done all over the country.

¶ 68 (emphasis added).

Defendant Carter's statements in the July 22 conference call were materially false and misleading because he repeated and reinforced his earlier statements that all "major" or "significant" FDA questions had been "retired." Further, he compounded the misleading impression of the status of the FDA's review of the NDA by denying that the Company owed any documents to the FDA that were required for its review and reprised his Class Period theme of blaming the delays on the FDA's excessive workload.

Perhaps Defendant Carter's most outrageous evasion of the truth was his response, at an investors' conference on September 9, 2009, to a question about the delay in FDA action, to which he responded: "I don't know. I'm not sure. Perhaps it's because the Commissioner's husband worked for a hedge fund [which owned Hemispherx shares]." Defendant Carter's

response shows his disregard of his obligations to impart truthful information to the Company's investors because he certainly knew, based on his extensive industry experience, that an FDA Commissioner would not play any role in making decisions about action on an individual NDA. ¶ 112. In fact, the main reason for the FDA delay was, as Defendants admitted on November 2, 2009, that there were numerous outstanding FDA requests for additional information to which Defendants were then responding and, as noted in the Complete Review Letter, multiple deficiencies in Hemispherx's NDA.

**2. Defendants' Misstatements Regarding the Safety and Efficacy of Ampligen**

Defendants also misrepresented that the Ampligen NDA satisfied FDA requirements, including statements that: (i) there were statistically significant results using what is called an intent to treat analysis from two controlled trials; (ii) there was clinical evidence that this drug, which was being used to treat a chronic condition, does not extend the QT interval (a measure of cardiac effect), and (iii) sufficient rodent carcinogenicity studies had previously been conducted, and therefore, it would be appropriate for the FDA to waive its requirement for such studies for the current NDA.

At the IACFS/ME 9th International Research and Clinical conference from March 12-15, 2009 in Reno, Nevada, Defendant Strayer made a presentation regarding Ampligen, in which he reported that there were no safety concerns from treatment with Ampligen:

> Interferon and cytokine levels in the phase III trial of Poly I: Poly C12U (ampligen) was presented by David Strayer (Philadephia, USA). Pre-treatment and intra-patient changes from baseline were compared to see if the treatment had a significant effect on serum levels. Patients had improved significantly in treadmill tests and decreased use of other medications with this treatment, but there was no significant modulation of interferons or cytokines. ***No safety concerns were raised*** and the treatment was well tolerated. The decrease in use of concomitant medications was an important point, as several of the medications

> used regularly in CFS do cause prolongation of the QT interval, with possible risk of death. ***Overall death rates in CFS patients due to heart failure, suicide and cancer were reduced.***

¶ 51 (emphasis added).

In the March 19, 2009 conference call, addressing the issue of the possible cardiotoxicity of Ampligen, Defendant Strayer said that:

> So what we did is we looked – again in the 516 study we looked we looked at the QT interval in the Ampligen group versus the placebo group. ***We actually found that the placebo group had a prolonged QT interval compared to the Ampligen group.*** We began to probe this. We found that it was directly related to the number of medications they were taking that prolong the QT interval.
>
> This was true in both AMP 502, our first randomized placebo-controlled study, as well as the second one, AMP 516.
>
> ***So these results really from two independent clinical trials suggest that the therapeutic benefit of Ampligen allows patients to reduce their dependence on concomitant medications used to treat the symptoms of CSF, and thereby specifically reducing exposure to these drugs that are known to prolong the QT interval.*** So we think this is a very important finding, and we have recently submitted this data to the Agency.

¶ 55 (emphasis added).

Defendant Strayer's statements that there were "no safety concerns" and that the use of Ampligen permits patients to reduce their dependence on other drugs which prolong QT interval (and have a negative cardiac impact) misled investors about the safety profile of Ampligen and the credibility of the Company's testing relating to cardiac side effects, which was an issue of primary importance to the FDA in considering any drug taken for long periods of time for chronic conditions. In fact, Defendants had merely re-analyzed data taken from previous trials completed in 1994 (AMP 502) and 1998 (AMP 516) to arrive at their conclusions about cardiac effects, which did not comply with FDA prescribed testing to determine the effect of a drug for a chronic condition on QT interval, as described in Guidance for Industry: Clinical Evaluation of

QT/QTC Interval Prolongation and Proarrhythmia Potential for Non-Antiarrhythmic Drugs. ¶ 57.

Defendant Strayer also stated during the March 19 call, in response to a question by a securities analyst, that the results for the "intent to treat" analysis of the treadmill time, the primary endpoint of Phase III Ampligen trial, "are statistically significant." ¶ 56. However, this was untrue because the p-value for that result was p=0.052, which is not statistically significant. ¶ 58.[25]

Unable to make any legal argument in the face of this undisputable fact, Defendants instead raise improper factual arguments. First, they *allege their own set of facts*, stating that the p-value for the treadmill test was actually 0.047 – not 0.052 as alleged in the Complaint. ¶ 37. Although Defendants acknowledge the "publicly disclosed audited results" from the trial, which showed a p-value of 0.052, Def. Br. at 18, they argue – in a footnote – that there was a "further audit" of the results which showed a p-value of 0.047 (which would be considered statistically significant). *Id.* at n. 27. At a minimum, Defendants' assertion of *new* facts not alleged in the Complaint raises a *factual dispute*, which entitles Plaintiffs to take discovery and to the determination of the factual dispute by the trier of fact. *See EEOC v. EMS Innovations, Inc.*, 06-cv-1320, 2007 U.S. Dist. LEXIS 990, at * 9 (D. Md. Feb. 12, 2007) (holding that consideration of matters outside the complaint would effectively convert the motion to dismiss to a motion for summary judgment, which would be denied in light of insufficient discovery).

[25] Hemispherx announced a p-value of 0.052 in press releases and never changed this in a press release or other widely disseminated, credible public communication. However, Defendants now cite a May 29, 2009 interview between StocksHaven.com (which appears to be a defunct website) and Defendant Carter in which Defendant Carter purportedly stated that the p-value was 0.047. *See* Def. Appendix Ex. 94. This interview, which is not cited in the Consolidated Complaint, cannot be considered by the Court in deciding Defendants' motion to dismiss and must be stricken because it is Defendants' private transcription of a purported interview attributed to a website which no longer exists. Thus, there is no evidence of the existence of this interview, much less any way to verify its contents.

Defendants' only support of the newly asserted "further audit" with a lower p-value is a transcript of an interview of Defendant Carter by StocksHaven Investments on May 29, 2009. Def. App. Ex. 94. This is highly improper for several reasons, and neither the transcript nor the "further audit" can be considered by this Court. *First*, the interview is not alleged or referred to anywhere in the Complaint. *See Jones v. Hashagen*, No. 4:09-CV-887, 2010 U.S. Dist. LEXIS 2328, at *13-14 (M.D. Pa. Jan. 12, 2010) (refusing to consider "matters outside the pleadings, a task which falls beyond the reach of a Rule 12 motion to dismiss" and noting that "[a] determination of such a factual dispute is improper at the motion to dismiss phase").

*Second*, there is no current evidence that this interview took place, except for Defendants' own privately commissioned transcription of it on February 22, 2010, four days before Plaintiffs filed their Consolidated Complaint, and almost nine months after the purported May 29, 2009 interview occurred. The audio version of the interview is presently unavailable, and the website, StocksHaven.com appears to be defunct. Thus there is no way to determine the authenticity or accuracy of the transcript. Courts may not consider documents outside the complaint when the authenticity is in dispute. *In re RAIT Fin. Trust Sec. Litig.*, No. 2:07-cv-03148, 2008 U.S. Dist. LEXIS 103549, at *14 (E.D. Pa. Dec. 22, 2008).[26]

*Third*, Defendants have improperly introduced this transcript for the truth of its contents. (Def. Br. at 18 n. 27 and 34). Even if the hurdles of establishing the existence of the interview and the authenticity of the transcript could be surmounted – which they cannot – this Court still cannot consider the transcript for the truth of its contents. *See, e.g., In re Vicuron Pharm., Inc.,*

[26] In deciding a motion to dismiss, a court may look to the allegations made in the complaint, any exhibits attached to the complaint and any documents "whose authenticity no party questions and whose contents are alleged in the complaint." *RAIT*, 2008 U.S. Dist. LEXIS 103549, at *14 (*citing Pryor v. Nat'l Collegiate Athletic Ass'n*, 288 F.3d 548, 560 (3d Cir. 2002). "Documents attached to a defendant's motion to dismiss may only be considered if they are referred to in the plaintiff's complaint and if they are central to plaintiff's claims." *Id.* at *14.

*Sec. Litig.*, No. 04-2627, 2005 U.S. Dist. LEXIS 15613 (E.D. Pa. July 5, 2005) ("Matters of public record . . . may not be considered for their truth, but only to determine what was said."); *In re NAHC, Inc. Sec. Litig.*, No. Civ. A. 00-4020, 2001 U.S. Dist. LEXIS 16754, at *5 (E.D. Pa. Oct. 17, 2001), *aff'd*, 306 F.3d 1314 (3d Cir. 2002); *In re Viropharma, Inc. Sec. Litig.*, No. Civ. A. 02-1627, 2003 U.S. Dist. LEXIS 1824914, at *1 (E.D. Pa. Apr. 7, 2003).[27]

### 3. Defendants' Pre-Class Period Disclosures Did Not Reveal the Facts that Defendants Concealed from Investors

Defendants claim that their Class Period statements (and material omissions) were not false and misleading because they had disclosed the facts before the Class Period. Def. Br. at 50. This contention must be rejected for at least two distinct reasons. *First*, as explained above, Defendants' truth-on-the-market defense is inappropriately and prematurely raised in the context of a Rule 12(b)(6) motion. *Second*, the purported disclosures cited by Defendants did not reveal to the investing public the complete facts that Plaintiffs have alleged were concealed – indeed, many of these statements were themselves incomplete disclosures and, thus, materially misleading.

Contrary to assertions in Defendants' "History of the Ampligen NDA," Def. Br. at 15-28, Defendants' pre-Class Period statements do not negate the false and misleading reasons given by Defendants for the delays of the PDUFA date that were announced during the Class Period. Any statements made by Defendants before the FDA accepted the Ampligen NDA for review on July 7, 2008, were entirely immaterial to the reasons for the delays of the PDUFA date more than

[27] For the same reasons, this Court may not consider as true Defendants' statement in a Form 8-K filed on May 26, 2009, attaching a press release issued on that date, Def. App. Ex. 35, that the "[r]eason for the possible delay was attributed by the Agency to certain staff scheduling changes which might (or might not) delay the report." Def. Br. at 34. SEC filings may only be considered "to determine what was said," but "not for their truth." *Vicuron*, 2005 U.S. Dist. LEXIS 15613, at *7.

seven months later.[28] Investors were aware that the NDA, as initially filed on October 11, 2007, was inadequate for review, and that Hemispherx had submitted substantial additional materials in order to complete its amended NDA on or about April 25, 2008. ¶ 38. However, when the NDA was accepted by the FDA on July 7, 2008, the investing public had no way of knowing about any then-existing or new deficiencies that could prevent approval of the NDA, which are considerations entirely separate from the factors which caused the FDA to accept the NDA as "complete."

In fact, Defendant Carter's statements during a July 17, 2008 conference call would have led investors to believe that any outstanding questions from the FDA had been put to rest approximately five months *before* the beginning of the Class Period. Specifically, he said that "the company is planning to answer remaining questions in the next 10 weeks so that ***by the end of September we will have – we believe we will have satisfied all the questions***. Some of you may remember there were earlier questions which were not critical for completeness but that remained important technical questions." Def. App. Ex. 72, at 1 (emphasis added).

Defendant Carter's pre-Class Period statements concerning cancer testing would also cause investors during the Class Period to believe that the Company's cancer testing was adequate and would not delay or prevent FDA approval. Def. Br. at 26-27. For example, Defendant Carter assured investors on July 17, 2008: "We believe we have more than adequate compelling reasons not to do any long term cancer studies and this comes from previous FDA decisions on closely allied drugs." *Id*. at 6. Moreover, Defendant Carter suggested that the worst case scenario would require the Company to perform such studies *after* securing FDA approval,

[28] The criteria for the FDA's decision to accept an NDA for filing purposes, Def. Br. at 7-8, are entirely different than those for review and approval of the NDA pursuant to the "PDUFA clock." Def. Br. at 9-14.

stating: "Our backup position is to accept this on a so called conditional basis, where we would do it at the same time we had our marketing approval . . . . So that is our backup position but we think it will probably not be necessary based upon the correspondence and based on the history." *Id*. Thus, even before the Class Period, investors had no reason to believe that additional carcinogenicity testing would be required in order to obtain FDA approval.

Defendants' pre-Class Period statements that Hemispherx had engaged Lovelace Respiratory Research Institute ("Lovelace") to perform animal toxicicty studies in support of the Ampligen NDA, Def. Br. at 27-28, *see also* Def. Appendix Ex. 7 and Def. Appendix Ex. 91,[29] are irrelevant in view of the fact that during the Class Period, on March 19, 2009, Defendant Carter stated that: "[W]e believe that we have answered all the major questions that have been put forward with the Agency," and that "the major questions which they have asked have in our opinion been retired." ¶ 52. Therefore, investors who purchased Hemispherx stock during the Class Period had no reason to expect that animal toxicicity studies could possibly be a factor for

[29] The Company's Form 10-Q for the third quarter of 2008 reported that the Lovelace studies would be completed in January 2009 – approximately one month before the start of the Class Period, stating:

> On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute . . . to perform certain animal toxic studies in support of our Ampligen® NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. ***We expect these studies to be complete in January 2009***.

Def. App. Ex. 7, at 20 (emphasis added). During a January 29, 2009 interview on a website called "Smallcaps.US," Defendant Carter claimed that unspecified animal tests would be completed in another 4 to 8 weeks, *i.e.*, no later than the end of March 2009:

> There are additional tests which are being conducted, and indeed these include animal tests to round out our preclinical toxicology package. We're projecting perhaps another four to eight weeks to complete those types of tests.

Def. Appendix Ex. 91, at 9.

delaying the FDA's decision on the Ampligen NDA.[30]

**E. Defendants' Misstatements Are Not Statements of "Belief and Opinion"**

Defendants contend that several of the misstatements alleged in the Complaint are merely statements of "belief and opinion" and are therefore not actionable. However, as demonstrated above, Defendants' misstatements and omissions concerned *facts*, not opinions, and therefore are actionable. Furthermore, to the extent that Defendants' statements were expressions of belief and opinion, they are actionable because Defendants knew them to be false when disseminated.

Defendants attempt to bolster their argument that the alleged misstatements are of "belief and opinion" by selectively quoting sections from the allegations where Defendants prefaced their statements with words such as "believe" and "think." However, merely beginning a sentence with the words, "I believe" does not magically transform a factual statement into a statement of belief and opinion. *See, e.g., In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 928 (D.N.J. 1998) (holding that the statement that "[Company] believes that the . . . acquisition will enhance its competitive position" was actionable).

*Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083 (1991) is the seminal case establishing that statements of belief or opinion could be actionable. There, the Court made clear that the doctrine it embodied pertains to statements that are not capable of being proved literally

[30] For example, although Defendant Carter noted on July 17, 2008 that animal toxicology testing was continuing, he stated that the results of such studies would be available in only 2 or 3 months, *i.e.*, no later than October 2008 – more than 4 months before the beginning of the Class Period. Specifically, Defendant Carter stated:

> With respect to your earlier question that dealt with other areas of animal toxicology, we are continuing a toxicologic program. One of our main partners in this is a group in the United States known as [Loveless] (inaudible), which is well recognized in this field and with which we have been working for several years. ***We basically expect those results to be available within the next couple, the next two to three months***. So we do not see any deterrent to a slowdown as a result of the free clinical toxicological program.

*Id*. at 6 (emphasis added).

true or false. The Court held that because statements of "judgment[] can be uttered with knowledge of truth or falsity just like more definite statements, and defended or attacked through the orthodox evidentiary process that either substantiates their underlying justifications or tends to disprove their existence," they could form the basis of a securities fraud claim. Implicit in this remark is the notion that a statement that *could* be objectively proven false, such as Defendants' claim that "we have answered all the major questions that have been put forward by the agency" are not statements of "opinion or belief," regardless of the fact that Defendants added the words "[w]e believe" to the beginning of the sentence.

The majority of statements Defendants categorize as "belief and opinion" can be confirmed as false, and therefore, are not "belief or opinion." For example, Defendants stated on more than one occasion that "[d]ue to constraints at the FDA, specifically and including the increased workload . . . work priorities may change resulting in the Agency going past the customary PDUFA goal set for reviews of an application." ¶¶ 47, 49. This statement did not suggest that Defendants merely believed that the FDA had an increased workload, but rather that delays in the FDA's review of the NDA were the result of the *fact* of the FDA's increased workload.

Defendant Strayer's representation in a March 19, 2009 conference call that the treadmill test showed "statistically significant" results is also a misstatement of material fact, and not a mere opinion. ¶ 56. Indeed, the reason why the scientific community measures statistical significance with p-values is to avoid any interjection of opinion or bias in the results.

Furthermore, Defendants have taken snippets from the alleged false or misleading statements quoted in the Complaint and used these snippets – devoid of any context – to

construct a "strawman" argument that these isolated phrases are inactionable statements of opinion or belief. Examples of these out-of-context snippets include the following:

- "[I]f they [the FDA] deem – if they have a question, they may- they may inspect again."
- "[O]bviously, Holister-Stier has an excellent reputation in this field, and we think that, ultimately, that will carry the day."
- I'm very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, which I believe is a very unusual positive result . . ."
- "[W]e believe that we will have achieved everything to the best of our knowledge which is necessary for a completion of what we call pre-approval inspections by the agency. So we would expect at any time thereafter to receive final comments from the FDA."

Def. Br. at 54-55. Defendants' construction of this "strawman" underscores the weakness of their argument.

Even assuming, arguendo, that Defendants' statements were ones of belief or opinion, such statements "if known to be false, may be the basis of a claim." *Hayes v. Gross*, 982 F.2d 104, 106 (3d Cir. 1992). As shown above, the Complaint alleges facts that show, among other things, the statements concerning the reasons for the FDA's delay as well as the statistical significance of the results were false. Furthermore, the statements concerning whether Defendants "answered" or "retired" the FDA's "major questions" were shown to be false when Hemispherx issued its November 2, 2009 press release in which Defendants admitted that, throughout the Class Period, they had been submitting numerous reports to the FDA on a variety of topics in response to ongoing FDA requests for additional information. ¶ 73. Moreover, as discussed more fully in the context of scienter, Defendants had actual knowledge of the falsity of their statements.

Finally, Defendants state that "no reasonable investor would interpret Dr. Carter's repeated, consistent, and cautious expressions of opinion or belief on the status of the FDA's

Ampligen review in the manner that plaintiff alleges." Def. Br. at 57. The suggestion that the investing public would not take Defendants at their word is disingenuous and incorrect. Indeed, "reasonable investors" relied upon Defendants to truthfully and accurately report on the status of the Ampligen NDA – the Company's most important project – and suffered economic harm when Defendants' statements were revealed to be false. Moreover, even sophisticated securities analysts that followed and reported on Hemispherx were misled by Defendants' statements. *TheStreet.com* published an article on November 3, 2009, after Defendants' partial disclosures, stating that investors were misled about the reasons for the FDA delay. ¶ 73. Furthermore, when Defendants revealed the truth, the price of Hemispherx stock dropped from $1.45 per share on October 30, 2009 to $1.13 on November 3, 2009, a decline of 23%. ¶ 74. The price of Hemispherx stock would not have declined so precipitously on the disclosure of the true facts regarding the reasons for the delay in the FDA's review of the Ampligen NDA if the market had not been misled by Defendants' statements.

### F. Defendants Are Not Shielded from Liability by the Safe Harbor

#### 1. Defendants' Statements Are Not Forward Looking

Defendants attempt to evade liability for their misstatements by asserting that some of these statements are forward-looking, and therefore, entitled to protection under the PSLRA safe harbor. Def. Br. at 59-64. However, Defendants cannot avail themselves of safe harbor protection because their misstatements were not forward-looking, nor were they identified as forward-looking and accompanied by meaningful cautionary language.

The PSLRA contains a statutory safe harbor for forward-looking statements that meet certain requirements. 15 U.S.C. §§ 78u-5. Under the safe harbor provision for written statements, "an issuer is not liable for a forward-looking statement if it is 'identified as a forward

looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." *EP Medsystems*, 235 F.3d at 873 (citing 15 U.S.C. § 78u-5(c)(1)(A)(I)); *see also Avaya*, 564 F.3d at 256. Similar requirements are enumerated in the safe harbor provision for oral forward-looking statements. 15 U.S.C. § 78u-5. *See City of Hialeah Employees Ret. Sys. v. Toll Bros., Inc.*, 2008 U.S. Dist. LEXIS 66906, at *11-*12 (E.D. Pa. Aug. 29, 2008) (the court finds that "Plaintiffs have adequately pled that any cautionary statements accompanying Defendants' written and oral projections were not meaningful in light of Defendants' alleged failure to disclose then-existing material facts.").

However, statements of past or present facts or circumstances (or omissions of material facts), are *not* forward-looking and, thus, are not covered by the safe harbor.[31] *See In re Cell Pathways, Inc. Sec. Litig.*, No. 99-752, 2000 U.S. Dist. LEXIS 8584, at *42 (E.D. Pa. June 21, 2000) ("'[A]llegations based upon omissions of existing facts or circumstances do not constitute forward looking statements'"); *Marsden v. Select Med. Corp.*, No. 04-4020, 2006 U.S. Dist. LEXIS 16795, at *24-25 (E.D. Pa. Apr. 6, 2006) (statements held to not be forward-looking because "Plaintiffs challenge these statements on the basis that Defendants withheld present information"); *In re Reliance Sec. Litig.*, 91 F. Supp. 2d 706, 721 (D. Del. 2000) (CEO's assurance to investors of company's current financial integrity were not forward looking statements); *Cal. Pub. Employees Ret. Sys. v. Chubb Corp.*, No. 00-4285, 2002 U.S. Dist. LEXIS 27189, at *33 (D.N.J. June 26, 2002) (holding that "purposeful omissions of existing facts or

[31] "[A] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." *Avaya*, 564 F.3d at 255 (quoting *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702 (7th Cir. 2008); *accord In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 213 (1st Cir. 2005) ("The mere fact that a statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement.")).

circumstances do not qualify as forward-looking statements"); *In re AOL Time Warner Sec. & "ERISA" Litig.*, 381 F. Supp. 2d 192, 223 (S.D.N.Y. 2004) (holding that "statements not contingent on future events" and not "projections about [a company's] financial future" are "statements of the Company's existing financial condition"); *MobileMedia*, 28 F. Supp. 2d at 930 (statement alleged to be misleading based on omissions of facts known to defendants did not qualify for safe harbor protection).

The safe harbor protection applies only to the following categories of statements: (1) "a statement containing a projection of revenues" or other financial items; (2) "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;' (3) "a statement of future economic performance;" and (4) "any statement of the assumptions underlying or relating to" the aforementioned statements. 15 U.S.C. § 78u-5(i)(1); *In re Viropharma, Inc., Sec. Litig.*, Civ. A. No. 02-1627, 2003 U.S. Dist. LEXIS 5623 (E.D. Pa. April 3, 2003). Based on the language emphasized by Defendants, it appears they believe the misstatements fall into category (2). Def. Br. at 59. However, the Complaint does not allege that Defendants misled investors about their "plans and objectives . . . for future operations," such as, for example, whether Hemispherx intended to vigorously pursue the Ampligen NDA, or even whether Hemispherx intended to conduct additional Ampligen studies.

Indeed, the statements identified as forward-looking, namely, that Defendants "expect[ed] definitive response letters" by May 25; that they "expect[ed] that sometime in the fall, perhaps sooner, [they would] be hearing from the agency;" and that it was their "expectation that these issues [would] be resolved . . . by the end of 2009," Def. Br. at 60, do not pertain to Defendants' "plans and objectives" for Hemsipherx. Similar misstatements concerning "the

current status of clinical trials and the NDA" submitted to the FDA have been found not to be forward-looking because "the truth or falsity" of the statements was "determinable at the time they were made." *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *25.

Furthermore, the mere fact that Defendants' misstatements appear in the same document as statements identified as forward-looking does not afford these misstatements safe harbor protection. The gravamen of the Complaint is not that Defendants misrepresented that the NDA would be approved, or even that they misrepresented the timing for the FDA's determination. Instead, the Complaint alleges that the Defendants misrepresented the *reasons* underlying the FDA's delay and the deficiencies in the NDA. The Court should not be distracted by Defendants' efforts to "pull isolated forward-looking statements out of the documents at issue in this case . . . . Simply because material misrepresentations appear in the same document as a forward-looking statement does not make the statements of fact eligible for the safe harbor." *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *26.

**2. <u>The Misstatements Were Not Accompanied by Cautionary Language</u>**

The question of whether purportedly "cautionary language" identified by Defendants is "sufficiently 'meaningful' raises fact issues that are improperly resolved" at the motion to dismiss phase. *Lucent*, 217 F. Supp. 2d at 557. Furthermore, Defendants face a high burden to identify appropriate cautionary language which "must be substantive and tailored to the specific predictions made in the allegedly misleading statement." *Id.* "Cautionary language must be 'extensive and specific.'" *Avaya*, 564 F.3d at 256 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004) (quoting *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)). "[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent

misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge." *Id.* (quoting *Semerenko*, 223 F.3d at 182).

Defendants cite two examples of purported cautionary language: (i) a Hemispherx "spokesperson" who recited boilerplate language prior to the March 19, 2009 and July 22, 2009 conference calls which stated that "the competition [completion] of the NDA filing process with Ampligen does not imply that the product will ever be approved commercially;" Def. Br. at 62, and (ii) language from the Form 10-K which states that "Ampligen may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale . . . We do not know when, if ever, Ampligen or our other products will be generally available for commercial sale . . . Generally only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale." However, both of these examples are precisely the type of "vague or blanket disclaimer" that does not qualify as meaningful cautionary language. *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 371-72 (3d Cir. 1993).

Finally, as with statements of belief and opinion, Defendants are not entitled to safe harbor protection where they already know their statements to be false. *In re Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *29 (holding that a defendant "may not use cautionary language to protect himself when he is already aware that the risks he is cautioning against have come to fruition").[32] No amount of cautionary language insulates such conduct from liability: "the safe

[32] *See also Eckstein v. Balcor Film Investors*, 8 F.3d 1121, 1127 (7th Cir. 1993) ("A prospectus stating a risk that such a thing could happen is a far cry from one stating that this had happened. The former does not put an investor on notice of the latter."); *MobileMedia*, 28 F. Supp. 2d at 930 ("Warnings of possible adverse events are insufficient to make omissions of present knowledge of certain future events legally

harbor will not apply if the statement was made with 'actual knowledge' that the statement was false or misleading." *Advanta*, 180 F.3d at 536; accord *Veritas*, 2006 U.S. Dist. LEXIS 32619, at *20 ("No manner of cautionary language can cure false statements knowingly made."). "In other words, the safe harbor provision does not afford corporations a free pass to lie to investors." *Veritas*, 2006 U.S. Dist. LEXIS 32619, at *20.[33] Here, as noted above, Defendants knew that the reason for the FDA delays was because of major problems in the Ampligen NDA.

**G. The Misstatements Are Material and Are Not Mere Puffery**

Defendants contend that the alleged misstatements constitute immaterial "puffery" and are therefore not actionable. Def. Br. at 66-68. Materiality determinations are generally not appropriate for a motion to dismiss. *See* Section III,A, *supra.*

Defendants argue that four statements are puffery. However, the following four statements were not alleged to be false and misleading by Plaintiffs: (1) "Yes, May 25, we would expect definitive response letters at that point;" (2) "[W]e expect that sometime in the fall, perhaps sooner, will be hearing from the – from the agency;" (3) "[O]bviously, Holister-Stier has an excellent reputation in this field, and we think that, ultimately, that will carry the day;" (4) "I am very pleased to say that the clinical inspections resulted in no findings which required corrective action by the Company, which I believe is a very unusual positive result." These statements do not form the gravamen of the Complaint, which is that Defendants misled

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immaterial."); *In re Nash Finch Co. Sec. Litig.*, 502 F. Supp. 2d 861, 873 (D. Minn. 2007) ("This Court concludes that cautionary language can not be 'meaningful' when defendants know that the potential risks they have identified have in fact already occurred, and that the positive statements they are making are false.").

[33] *See also Gargiulo v. Demartino*, No. 06-01741, 2007 U.S. Dist. LEXIS 71316, at *15 (E.D. Pa. Sept. 26, 2007) ("Thus, though some of the statements are forward-looking and contain cautionary language, they are still not protected by the PSLRA safe harbor because Plaintiffs allege that Defendants had actual knowledge of falsity (stating that the safe harbor protection would not apply if the plaintiff proved that there was actual knowledge that the statement was false or misleading.")).

investors about the *reasons* for the FDA delays, and not about the exact date on which the FDA would be issuing a decision. The fifth statement cited by Defendants concerning "no corrective action" following FDA inspections deals with Hemispherx's ability to manufacture Ampligen on a commercial level, and is not relevant to the allegations in the Complaint that Defendants misled investors by failing to disclose that the reason for the delay in the FDA review was because of efficacy and toxicology shortcomings with Ampligen.

Furthermore, to the extent these statements were misleading – and they were, because, in fact, Defendants knew that there were substantial deficiencies with the Ampligen NDA that would not permit an FDA response by May 25, or the fall, and that Holister-Stier's contributions could not overcome the problem of inadequate efficacy and safety data – such statements were not merely puffery. To constitute puffery, a statement must be a "statements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism." *EP Medsystems, Inc*, 235 F.3d at 872. Thus, there is some overlap between statements of puffery and statements of belief or opinion. However, none of the statements Defendants categorize as puffery are "general statements of optimism" or suggest an opinion, motive or intention of their speakers.

## H. Plaintiffs' Allegations Raise a Compelling Inference of Defendants' Scienter

### 1. Plaintiffs' Allegations Must Be Considered Holistically in Determining Whether They Raise a Strong Inference of Scienter

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. 308, 319 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193-94 (1976)). Under the pleading requirements of the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" in

order to establish the element of scienter. 15 U.S.C. § 78u-4(b)(2); *Avaya*, 564 F.3d at 267. This scienter standard requires plaintiffs to allege facts giving rise to a "strong inference" of "either reckless or conscious behavior." *Avaya*, 564 F.3d at 267 (quoting *Advanta*, 180 F.3d at 534-35).

The PSLRA requirement that the plaintiff plead with particularity facts giving rise to a "strong inference" of scienter requires courts to weigh the "plausible nonculpable explanations for the defendant's conduct" against the "inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 324. A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id*. at 314; *see also id*. at 316 ("The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the most plausible of competing inferences."). The question is "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id*. at 323; *see also id*. at 326 ("[T]he court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically."). *See Avaya*, 564 F.3d at 267.

As the Third Circuit stated in *Avaya*:

> Accordingly, as with all totality-of-the-circumstances tests, our analysis will be case specific. It will ultimately rest not on the presence or absence of certain types of allegations but on a practical judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as not that defendants acted with scienter. *See South Ferry LP v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) ("*Tellabs* counsels us to consider the totality of circumstances, rather than to develop separately rules of thumb for each type of scienter allegation."); *see also In re Cabletron Sys., Inc*., 311 F.3d 11, 32 (1st Cir. 2002) ("Each securities fraud complaint must be analyzed on its own facts; there is no one-size-fits-all template.").

564 F.3d at 269. The Third Circuit continued:

> But inference is not arithmetic. The inferential significance of any single allegation can be determined only by reference to all other allegations.

*Avaya*, 564 F.3d at 273. The Third Circuit's analysis concluded:

> Although we have discussed each of the alleged facts bearing on defendants' scienter one at a time, we have heeded *Tellabs's* command to evaluate Shareholders' allegations collectively rather than individually. As we have taken up each allegation in turn, we have added it to the picture painted by the previously considered allegations and asked: How does this addition affect the relative strengths of the culpable and non-culpable inferences?

*Id*. at 280.

**2. The Complaint Alleges Conscious Misbehavior and/or Recklessness**

The Complaint sets forth multiple categories of allegations that, taken collectively, require a finding that Defendants' intentionally or recklessly misled investors is the most cogent and compelling inference for their misstatements concerning the reasons why the FDA was delaying its review of the Ampligen NDA.

**a. Defendants,' as the Top Executives of the Company, Raise an Inference of Their Knowledge of the Company's Core Product Ampligen**

The Complaint alleges that Defendant Carter was Chairman of the Board of Directors at Hemispherx and Chief Executive Officer since the earlier 1990s. ¶ 21. Furthermore, Defendant Carter was the co-inventor of Ampligen and has worked at Hemispherx since 1978. *Id.* Defendant Strayer has been the Medical Director of Hemispherx since 1986. ¶ 22. Because of Defendants Carter's and Strayer's high-ranking positions – in addition to the fact that Defendant Carter invented Ampligen – the Court should infer that they had full knowledge of all the facts surrounding the Ampligen NDA, including communications with the FDA and any reasons for the delay in the review of the NDA. When a high-ranking officer or director of a company makes a public statement regarding "core operations" of the company, and that statement turns

out to be false, courts often infer that the speaker knew the statement was false when made.[34] *See Avaya*, 564 F.3d at 270 ("Given the specificity and repetition of the analysts' questions, McGuire's position as Chief Financial Officer, and the alleged state of Avaya's business at the time the questions were asked, there is a strong inference that McGuire's behavior reached this threshold of recklessness."); *In re RAIT Fin. Trust Sec. Litig.*, No 2:07-cv-03148-LDD, 2008 U.S. Dist. LEXIS 103549, at *50 (E.D. Pa. Dec. 22, 2008) ("Because the alleged misstatements involved RAIT's core business operations and because the Officer Defendants had ample reason to know of the falsity of their statements, there is a strong inference of scienter in this case.").[35]

As noted, Defendants Carter and Strayer were high-ranking officers of Hemispherx, and therefore, knowledge of the Company's key operations and core products can be imputed to them. Indeed, Defendants themselves admit that Defendant Carter was knowledgeable about the key facts underlying the Complaint when they state that Hemispherx's success "is dependent on

[34] The cases cited by Defendants do not refute this proposition, and in fact, several of them reinforce that courts may impute knowledge of a key product to high-ranking officials. *See In re Stonepath Group, Inc. Sec. Litig*., Civ. A. No. 04-4515, 2006 U.S. Dist. LEXIS 25250, at *34 (E.D. Pa. Apr. 3. 2006) (noting that "[o]ur courts have repeatedly held . . . that knowledge of core activities of a business may be imputed to its highest officials in some circumstances"); *City of Roseville Employees Ret. Sys. v. Horizon Lines, Inc.*, Civ. A. No. 08-969, 2009 U.S. Dist. LEXIS 106186, at *53 (D. Del. Nov. 13, 2009) (noting that "it is true that false or misleading statements by key executives regarding a company's lead product or core business practice will weigh in favor of finding a strong inference of scienter"); *Grover v. DeLuca*, 2006 U.S. Dist. LEXIS 76093, at *32 (W.D. Pa. Sept. 9, 2006) (holding that because scienter allegations regarding accounting violations failed because there were no allegations concerning the insiders' intent to defraud the public concerning the company's financial statements).

[35] *See In re Tel-Save Sec. Litig.*, No. 98-CV-3145, 1999 U.S. Dist. LEXIS 16800 (E.D. Pa. Oct. 19, 1999) (where one director personally and often solely negotiated some transactions and participated in many others that were a significant part of the company's business); *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999) (knowledge of "widespread integration problems" following an $8.9 billion merger imputed to top corporate officers); *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001) (where defendants participated in discussions about improper company practices during which others expressed reservations about those practices and called for them to stop); *In re Viropharma Inc. Sec. Litig.*, 2003 U.S. Dist. LEXIS 5623, at *31 (E.D. Pa. Apr. 3, 2003) (where pharmaceutical company's highest ranking members undisputedly had access to clinical trial reports questioning the efficacy and safety of a drug); *In re Loewen Group Inc. Sec. Litig*., No. 98-6740, 2004 U.S. Dist. LEXIS 16601, at *67 (E.D. Pa. Aug. 18, 2004) (where a plaintiff pleads alleged fraud concerning a corporation's core business and the defendant held a position from which he would have been aware of the true facts and misleading disclosures, scienter is pleaded sufficiently); *In re Vicuron Pharms., Inc. Sec. Litig*., No. 04-2627, 2005 U.S. Dist. LEXIS 15613, at * 18 (E.D. Pa. July 1, 2005) (where key officers and directors knew or must have known of false or misleading statements because the statements involved the company's lead product).

the continued efforts of . . . Dr. William A. Carter because of . . . his being the co-inventor of Ampligen, and his knowledge of [Hemispherx's] overall activities, including patents and clinical trials." ¶ 87.

Furthermore, there can be no dispute that Ampligen was not only the "core product" of Hemispherx, but the Company's entire future rested on the success of Ampligen's NDA. Defendants admit in SEC filings that Ampligen represents "one of the Company's 'two core pharmaceutical platforms.'" ¶ 43. The Complaint further alleges that Defendants acknowledged that Ampligen was the "core product" of Hemispherx during various analyst calls preceding and during the Class Period. For example, the Complaint makes the following allegations:

- During the December 17, 2007 analyst call, Defendant Carter noted that royalty interest for Pfizer's drug used to treat the "sister disease" of CFS sold for $700 million and that Ampligen's potential treatment of CFS therefore "holds great economic benefit" and would be a "bountiful harvest for the company who ultimately succeeds." ¶ 98.

- During the April 9, 2008 analyst call, Defendant Carter stated that potential strategic alliances with others looking to treat CFS were "big enchiladas." ¶ 99.

- During the July 17, 2008 analyst call, Defendant Carter presented statistics concerning the millions of patients with CFS and noted that Ampligen was the "only product" with "advanced clinical data" showing it could potentially treat the "constellation of symptoms" of CFS, and noting that the fibromyalagia drugs were projected to generate annual revenues of between $2.0 billion and $2.4 billion. ¶ 100.

- Also during the July 17, 2008 analyst call, Defendant Carter stated that during the "long road" to getting FDA approval for Ampligen, "a lot of money has been spent." Furthermore, he stated that when Hemispherx first licensed Ampligen from Johns Hopkins University was a "very critical point in [the Company's] history." ¶ 101.

- During the March 19, 2009 analyst call, Defendant Carter stated that Hemispherx resources originally earmarked for its other product, Alferon, were "redeployed for [a] major undertaking in the Ampligen New Drug

Application," and that this was necessary because Ampligen had the potential to be a $1 billion product. ¶ 102.

Therefore, the Court can infer that Defendants had knowledge regarding the circumstances of the Ampligen NDA. As the Seventh Circuit found in *Makor Issues & Rights Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 707-09 (7th Cir. 2008), alleged statements concerning the company's "flagship" product make an inference of innocence "exceedingly unlikely." The court reasoned "[t]hat no member company's senior management who was involved in authorizing or making public statements about the demand for the [core product] knew that they were false is very hard to credit, and no plausible story has yet been told by the defendants that might dispel our incredulity." *Id.* at 709. Similarly, here, an inference that Defendants did not know that the true reasons for the FDA delays – that the Company had numerous outstanding issues to which it had to respond – is "exceedingly unlikely."

**b. Defendants' Knowledge Regarding Safety and Efficacy**

The Complaint alleges that Defendants knew that Ampligen would require additional carcinogenicity studies and additional clinical trials in order to prove safety and efficacy for Ampligen. ¶¶ 41-43. The Complaint sets forth the following facts in support:

- During a December 3, 2009 analyst call, Defendants disclosed that the FDA had rejected Ampligen's NDA, in part because further clinical studies regarding efficacy were required, Defendant Carter stated that this news was "not unexpected" and cited Pfizer's need to perform a third study for a drug that treated a "sister disease" to CFS. ¶ 88.

- Despite the fact that Defendant Carter knew of the likelihood that Ampligen would require additional clinical trials since at least April 2008, Defendant Carter repeatedly told investors that no such trials were required. ¶¶ 89-90.

- During the December 3, 2009 conference call, Defendant Carter stated that the Company had already "engaged [contract research] organizations to facilitate enrollment of patients for the third clinical trial prior to receiving

the FDA's complete review letter," which is strong evidence that Defendants knew an additional clinical trial would be required. ¶¶ 91-92.

- Defendants also knew that Hemispherx needed to perform carcinogenicity studies because it had requested a waiver from such studies, and was denied. ¶ 93. Despite Hemipherx's inability to complete the required carcinogenicity studies, Defendant Carter stated in May and June 2009 that no further studies were required. ¶ 93.

Defendants argue that the Complaint did not include allegations of contemporaneous facts to demonstrate that they possessed knowledge of the falsity of their statements during the Class Period. Def. Br. at 70. However, the Complaint's allegations that Defendant Carter knew *since at least April 2008* that Ampligen would require additional studies of its safety and efficacy constitutes knowledge held during the Class Period as well. Defendants next argue that Plaintiffs improperly rely upon Defendant Carter's April 9, 2008 statement, made ten months before the beginning of the Class Period, and note that "plaintiff averred no particularized facts showing that this statement was either objectively or subjectively false when made." Def. Br. at 71. However, the statement was highlighted in the scienter section of the Complaint, ¶ 90, and was set forth as background. It therefore does not form the basis of a misleading statement allegation. The paragraph in the Complaint goes on to state that Defendant Carter knew that Ampligen would require efficacy studies because, during that same April 9, 2008 analyst call, he stated that the "sister disease" of fibromyalgia required a third clinical trial. ¶ 89.

Defendants also fault the allegations concerning Pfizer's drug for fibromylagia because they do not allege that Defendant Carter "actually knew" the FDA would require Hemispherx to conduct a third efficacy study. Def. Br. at 72. However, this allegation, taken collectively with all the other allegations, gives rise to a strong inference of scienter.

Finally, Defendants argue that the allegations concerning knowledge of the carcinogenicity study do not support an inference of scienter because Defendants did not receive word from the FDA that its waiver request was denied until December 1, 2009. Def. Br. at 72-73. Since Defendants had requested that waiver in October 2007, it is reasonable to infer that Defendants knew – or were reckless in not knowing – that such a request would be denied, considering their vast experience, the numerous conversations they had with the FDA and the fact that the FDA never *approved* the request. Any competing inference is "exceedingly unlikely" and implausible.

**c. Defendants' Dealings With the FDA During the Class Period**

The Complaint alleges that the FDA approval process is set up in such a way to encourage and even require frequent communication with an applicant during the NDA approval process. ¶¶ 106-111. Such allegations, taken directly from FDA publications explain that, for example, the FDA requires "[e]ffective and timely communication between the FDA and applicants," particularly concerning NDA deficiencies and that "[t]imely notification of correctable deficiencies allows the applicant to begin corrective actions, maximizes the chances for a first cycle approval, and shortens the overall time to approval when one or more review cycles are necessary." ¶ 107. Given the FDA's stated objectives concerning "notification of deficiencies" and providing applicants with realistic "expectations" of decisions, ¶ 106, it would strain credulity to believe that, for example, the FDA remained silent – for more than two years – on Hemispherx's request for exemption from the carcinogenicity studies, or that the FDA never raised any concerns regarding cardiac safety or proof of efficacy.

**d. Defendants' History of Reprimands From the FDA Concerning False Statements About Ampligen and Defendant Carter's Communications with the FDA**

The Complaint contains allegations that Defendant Carter was the principal communicator with the FDA during the approval process for Ampligen's NDA. In particular, the Complaint alleges that a confidential witness who worked closely with Defendant Carter in an administrative capacity from 1999 through the end of 2008 declared: "That Dr. Carter tightly controlled the communication channel between Hemispherx and the FDA is an understatement. Everything went through him or not at all." ¶ 86. Defendants do not meaningfully challenge that this statement goes to Defendant Carter's knowledge of the application process, but merely conclude that it is insufficient to "establish scienter under the PSLRA." Def. Br. at 75. However, statements of confidential witnesses are valuable, and courts often recognize that they can create a strong inference of scienter. *See In re RAIT Fin. Trust Sec. Litig.*, 2008 U.S. Dist. LEXIS 103549 at *49-50 (finding that plaintiff met the PSLRA standard for scienter in part based on statements from confidential sources); *Tellabs Inc.*, 513 F.3d at 711 ("The 26 'confidential sources' referred to in the complaint are important sources for the allegations not only of falsity but also of scienter."); *see also Avaya*, 564 F.3d at 264 (relying upon allegations from confidential witnesses to find that plaintiffs had pled false statements).

The Complaint further alleges that the FDA has historically communicated directly with Defendant Carter. ¶¶ 113-115. Specifically, in 1998, the FDA issued a reprimand to Defendant Carter that it had "determined that Hemispherx is promoting Ampligen as a safe and effective drug prior to its approval for marketing. Promoting drugs prior to their approval violates the Food, Drug, and Cosmetic Act . . . . Hemispherx should immediately discontinue the dissemination of materials that make claims of safety or efficacy of Ampligen." ¶ 113. Despite

this warning, Defendants continued to make claims publicly about Ampligen's safety and efficacy, prompting the FDA to issue another warning letter to Defendant Carter in 2000, stating: "[N]otwithstanding your assurances, you continue to promote Ampligen as safe and effective prior to approval . . . ." ¶ 114.

The Complaint alleges that such communications establish that Defendant Carter played a central, hands-on role in the Company's communications with the FDA and in seeking approval for Ampligen. ¶ 115. Defendants argue that such allegations do not support an inference of scienter because they fall outside the Class Period. Def. Br. at 77. However, these facts support the inference that Defendant Carter had a central role in dealing with the FDA, and was knowledgeable about the Company's communications with the FDA as well as the status of the NDA during the Class Period.

**3. The Complaint Alleges That Defendants Had Motive and Opportunity to Commit Securities Fraud**

Although motive and opportunity to commit fraud "may no longer serve as an independent route to scienter," *Avaya*, 564 F.3d at 277, the Complaint includes a myriad of allegations concerning Defendants' motives and opportunity. "Motive entails allegations that the individual corporate defendants stood to gain in a concrete and personal way from one or more of the allegedly false or misleading statements and wrongful nondisclosures." *In re RAIT Fin. Trust Sec. Litig.*, 2008 U.S. Dist. LEXIS 103549, at *51-*52 (E.D. Pa. Dec. 22, 2008) (quoting *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 633 (D.N.J. 2002) (citing *Novak v. Kasaks*, 216 F.3d 300, 307 (2d Cir. 2000); *Phillips v. LCI Int'l, Inc.*, 190 F.3d 609, 621 (4th Cir. 1999); *In re Nice Sys., Ltd. Sec. Litig.*, 135 F. Supp. 2d 551 (D.N.J. 2001)). *See also Avaya*, 564 F.3d at 279

("plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud.")).

**a. Defendant Carter's Standby Financing Agreement**

Defendant Carter had a concrete, personal motive to commit securities fraud. In February 2009, he entered into a Standby Financing Agreement with Hemispherx, in which he agreed personally to loan the Company up to $1 million to maintain its operations if it were unable to secure alternative funding, such as through securities offerings or outside financing agreements. ¶ 83. Therefore, Defendant Carter was motivated to mislead investors regarding the Ampligen NDA so that Hemispherx could raise money without his need to loan personal funds to the Company.

Defendants misconstrue these allegations and assert that these averments "actually ***negate*** any inference of scienter." Def. Br. at 79 (emphasis in original). Defendants cite additional terms of Defendant Carter's contract with Hemispherx, which provide the Company will grant him 10-year warrants to purchase common stock in consideration for his entering into the Standby Agreement and the Company would issue him secured notes with interest paid in common stock in the event the loan became necessary. *Id.* However, such provisions do nothing to negate his motive of not wanting to loan the funds in the first place. Furthermore, if circumstances were so dire that he as required to loan the funds, it is likely that the Company's stock price would drop dramatically, and such stock warrants would be worth very little. Finally, Defendants' observation that Defendant Carter's motives with regard to the stock warrants "remained aligned with that of Hemispherx's shareholders, regardless of whether he executed a personal loan," Def. Br. at 79-80, is inapposite. Whatever "generalized motives" Defendant

Carter may have shared with other shareholders would have had no effect on the personal, concrete motive he had to avoid making the loan.

Finally, Defendants misconstrue the entire nature of Plaintiff's theory of scienter regarding the Standby Loan Agreement, which is not that Defendant Carter "attempted to jeopardize the Company's long-term success," but rather that he perpetuated the fraud for as long as possible to allow the Company to obtain outside financing, so that when the truth inevitably came out – as Defendant Carter knew it would when the FDA finally issued its complete review letter – he was not left holding thousands of shares of worthless Hemispherx stock and warrants in exchange for the loan.

**b. Hemispherx's Class Period Securities Offerings**

The Complaint alleges that Defendants were motivated to commit securities fraud in order to artificially boost the prices of Hemispherx common stock, in connection with the Class Period securities offerings. ¶¶ 84-85. In particular, pursuant to two securities purchase agreements dated May 8, 2009 and May 18, 2009, Defendants raised approximately $33.7 million for the Company.

Furthermore, Defendants had entered into a $30 million Common Stock Purchase Agreement with Fusion Capital Fund II, LLC on July 2, 2008. Pursuant to that agreement, Hemispherx had the right, over a 25 month period beginning in August 2008, to sell its stock to Fusion Capital up to a maximum of $30 million. The price of the shares was based on the prevailing market prices as of July 2, 2008. If the price of Hemispherx stock fell below $0.40 per share, however, Fusion Capital was not obliged to purchase the stock. As of September 1, 2009, Fusion Capital had purchased the maximum number of shares permitted under the

Common Stock Purchase Agreement and Defendants raised $28.1 million for the Company. ¶ 84. Combined, these securities offerings netted the Company almost $62 million. ¶ 85.

Defendants argue that these allegations are nothing more than "generalized motives . . . widely held by corporations and their executives" and therefore cannot support an inference of scienter. Def. Br. at 78-79. However, the Complaint alleges that such funds were necessary for the very survival of the Company, and therefore amount to more than simple motives to "maintain a high stock price" as Defendants and the cases they cite suggest.[36]

Defendants contend that motivations to raise capital do not support an inference of fraud. Def. Br. at 79. However, this motivation must be considered holistically with the numerous other scienter allegations in the Complaint. In *Tellabs*, 513 F.3d at 708, the Seventh Circuit explained that a motive to benefit the corporation can be both compelling and cogent. *See also In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1097 (9th Cir. 2002) ("plaintiffs are correct that a desire to raise company financing can be probative of a motive to defraud investors.") *See also Southland Sec. Corp. v. InSpire Ins. Solutions, Inc.*, 365 F.3d 353, 366 (5th Cir. 2004). In fact, Defendants' desire to artificially inflate the Company's stock price can serve as compelling and cogent evidence of scienter. *See, e.g.*, *In re MicroStrategy*, 115 F. Supp. 2d 620, 647-48 (E.D. Va. 2000) (the success of the company's IPO and SPO based upon false statements contributed to finding of scienter); *In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294, 317 (D. Mass. 2006) (a strong inference of scienter was found where plaintiffs alleged that defendants were motivated to delay an impairment charge in order to complete a stock offering); *In re Am. Bank Note*

[36] The cases cited by Defendants are inapposite. *See In re Discovery Labs. Sec. Litig.*, Civ. A. No. 06-1820, 2006 U.S. Dist. LEXIS 79823 (E.D. Pa. Nov. 1, 2006) (involving "equity financing agreements" not alleged to be necessary for the very survival of the Company); *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242 (3d Cir. 2009) (involving a credit facility that was not tied to the price of defendant corporation's stock); *ECA & Local 132 IBEW Joint Pension Trust of Chicago v. J.P. Morgan Chase Co.*, 553 187, 200 (2d Cir. 2009) (relating to acquisition of another company).

*Holographics Sec. Litig.*, 93 F. Supp. 2d 424, 444-45 (S.D.N.Y. 2000) ("[Defendant company] had the most to win by inflating the price of the IPO, and was thus motivated to make statements or omit facts that would result in a higher price."); *In re Centocor, Inc. Sec. Litig. III*, No. 98-260, 1998 WL 964184, at *3 (E.D. Pa. Dec. 1, 1998) (scienter was adequately pled where plaintiffs alleged that defendants wanted to complete a public offering).

**c. Defendants' Bonus Compensation**

The Complaint alleges that Defendants Carter and Strayer had a concrete and personal motive to commit securities fraud because they were entitled to receive substantial incentive-based cash awards for causing the NDA to be filed and raising cash by misleading investors about the Ampligen NDA. In particular, Defendant Carter was awarded $300,000 and Defendant Strayer $150,000 for these actions on May 29, 2009. ¶ 104. Defendant Carter was additionally awarded a 2009 year-end bonus of $182,772 – the largest granted by Hemispherx to any employee – and Defendant Strayer was awarded a year-end bonus of $44,306, representing the second-largest such award even after the FDA denied the NDA for Ampligen. ¶ 105.

**I. The Complaint Adequately Pleads A Section 20(a) Claim Against The Individual Defendants**

Plaintiffs allege a claim under Section 20(a) of the Exchange Act against the Individual Defendants. Section 20(a) creates a cause of action against individuals who exercise control over a "controlled person," including a corporation, that has committed a violation of Section 10(b). 15 U.S.C. § 78t(a); *Avaya*, 564 F.3d at 252; *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284 (3d Cir. 2006). Accordingly, liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person. *Avaya*, 564 F.3d at 252 (citing *In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 153 (3d Cir. 2004) ("[P]laintiffs must prove not only

that one person controlled another person, but also that the 'controlled person' is liable under the Act.")).[37]

Defendants do not argue that they are not control persons. Rather, they merely argue that the Complaint did not allege an underlying Section 10(b) violation, and so it failed to allege a derivative claim under Section 20(a). Def. Br. at 81. Because of the derivative nature of the claim, if the Court finds that the Complaint alleges a Section 10(b) claim, it must also conclude that it alleges a Section 20(a) claim against Defendants Carter and Strayer.

### J. In The Alternative, The Court Should Grant Plaintiffs Leave To Amend The Complaint

If the Court concludes that Plaintiffs did not successfully plead any of the foregoing claims, Plaintiffs request leave to amend the Complaint. Rule 15(a) of the Federal Rules of Civil Procedure requires leave to amend a pleading to be "freely given when justice so requires." *See also Ellis v. Chao*, 336 F.3d 114, 127 (2d Cir. 2003); *Ruggles v. Wellpoint, Inc.*, No. 1:08-CV-201, 2009 U.S. Dist. LEXIS 99548, *6-7 (N.D.N.Y. Oct. 14, 2009) (granting plaintiff's motion to amend). Leave to amend should be denied only in the face of undue delay, bad faith, undue prejudice to the non-movant, futility of amendment, or where the movant has repeatedly failed to cure deficiencies in previous amendments. *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962); *Kropelnicki v. Siegel*, 290 F.3d 118, 130 (2d Cir. 2002) (*citing Chill v. Gen. Elec. Co.*, 101 F.3d 263, 271-72 (2d Cir. 1996)). It is Defendants' burden to establish that Plaintiffs' request for leave to amend should have been denied. *See New York v. Panex Indus.,*

[37] Once an inference of control is raised, the burden shifts to defendants to establish lack of culpable participation or knowledge. *See Maher v. Durango Metals, Inc.*, 144 F.3d 1302, 1305 (10th Cir. 1998). Furthermore, issues of control liability are highly fact intensive and are "not ordinarily resolved summarily at the pleading stage." *In re Cabletron Sys., Inc.*, 311 F.3d 11, 41 (1st Cir. 2002) (recognizing that "the issue raises a number of complexities that should not be resolved on such an underdeveloped record"). In fact, courts have held that dismissal of a section 20(a) claim should only be granted where a "plaintiff does not any facts from which it can reasonably be inferred the defendant was a control person." *Maher*, 144 F.3d at 1306.

*Inc.*, 94-cv-0400, 1997 U.S. Dist. LEXIS 3163 at *2 (W.D.N.Y. Mar. 14, 1997) ("The party opposing a motion for leave to amend has the burden of establishing that granting such leave would be unduly prejudicial.") (*citing Saxholm AS v. Dynal, Inc.*, 938 F. Supp. 120, 123 (E.D.N.Y. 1996)); *see also Lamont v. Frank Soup Bowl*, 99 cv 12482, 2000 U.S. Dist. LEXIS 18550, at *2 (S.D.N.Y. Dec. 27, 2000) (citations omitted). This requires the Defendants to "do more than simply claim to be prejudiced." *Bryn Mawr Hosp. v. Coatesville Elec. Supply Co.*, 776 F. Supp. 181, 185 (E.D. Pa. 1991). Defendants would not be able to satisfy their burden in this case. There is no bad faith on the part of Plaintiffs. Furthermore, at this early stage of the litigation, before discovery, there would be no undue delay or prejudice to Defendants should Plaintiffs' motion for leave to amend be granted.

## IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss the Plaintiffs' Complaint should be denied in its entirety, or in the alternative, Plaintiffs' request for leave to amend the Complaint should be granted.

Dated: March 26, 2010

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing Plaintiffs' Brief in Opposition to the Motion to Dismiss the Class Action Complaint was filed through the ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and electronically sent to those indicated as non-registered participants on April 1, 2010.

*/s/Barbara A. Podell*
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